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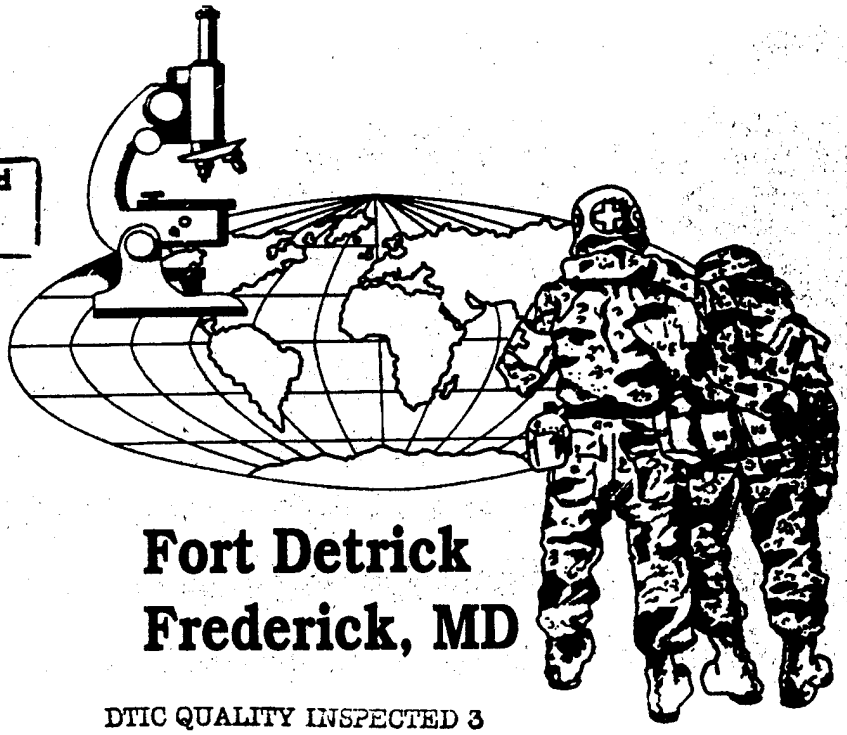
1994 ANNUAL REPORT



Fort Detrick
Frederick, MD

1994 ANNUAL REPORT

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FORT DETRICK
FREDERICK, MARYLAND 21702-5009

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U.S. ARMY
MEDICAL MATERIEL DEVELOPMENT ACTIVITY
1994 ANNUAL REPORT
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COMMANDER'S LETTER

In 1994, USAMMDA completed its first decade as the DOD's Principal Medical Materiel Developer. No year since 1984 has been as dynamic and challenging. Changes and challenges included: directed manpower and dollar reductions; establishment by DOD of a Joint Program Office (JPO) for Biological Defense to oversee continuing biological defense vaccine development; repeated attacks on the integrity of military medical R&D by the Rockefeller Commission's inquiry into the use of investigational products during Operation Desert Storm. These changes were overlaid on a healthy anxiety infused into the whole Command by several new faces and personalities at our Headquarters, including a new Commanding General, Brigadier General Russ Zajtchuk, and a new Deputy Commander and Chief of Staff.

To meet these challenges, we began several management initiatives and continued others begun in previous years, such as our business planning process and a reengineered Milestone 0 process. We also made dramatic changes in core philosophies of fiscal and regulatory management, empowered product managers, and implemented strategic planning to best meet warfighter needs and priorities in the face of resource reductions.

In early 1994, the USAMMDA underwent its first-ever manpower reduction action. That action ultimately will affect 21% of our civilian and 50% of our military positions. Clearly, USAMMDA is doing its part to help balance the budget!

Staff reductions planned in 1994 for implementation over the next five years will challenge us to rightsize USAMMDA to retain core capabilities and functions. So far, trade-offs in our 1995 - 1999 plan include our in-house medical device Testing and Evaluation capability, our in-house entomological and optometric product management capabilities, senior levels of management in our Support Division, scaled back engineering and biomedical product management, logistics management, and visual and graphic arts capabilities.

Resource drills were problematic throughout the year. Most significantly, USAMMDA was tasked to pay a 3-year, $11 million bill for Telemedicine. This 10 - 13% annual reduction required we accept maximum acceptable risks in developing products and terminate the lowest priority product, Microencapsulated Antibiotic Ampicillin-Dental. Other products will be terminated next year in order to maintain accelerated activity on the highest priority products. Better forecasting, risk assessment and management, and intense fiscal oversight will be used to assure we meet or exceed all cost, schedule, and performance objectives for the highest priority products. The management tools necessary to accomplish these actions are now available to USAMMDA managers in the form of well-conceived resourcing strategies and business plans.

The DOD's establishment of a Joint Program Office for Biological Defense (JPO-BD) significantly challenged our "comfort level" during the last half of 1994. This Program was charged with responsibility for all BD vaccine development, and USAMMDA became its sole vaccine developer. Through the JPO-BD, we became direct partners with the non-medical Materiel Developers in the U.S. Army Materiel Command, SARDA, ATSD(Atomic Energy), Army DCSOPS, and others previously shielded as much from our view as we were from theirs. Such high-level DOD and Army oversight of our development program required we focus much more clearly on DOD acquisition policies and Materiel Developer responsibilities and obligations. While uncomfortable at first, a relationship between USAMMDA and the JPO grew out of necessity and, at year's end, is becoming functional and successful.

In mid-year, the Rockefeller Commission challenged the DOD medical community on its practice of using investigational products developed by USAMMDA to protect soldiers from biological and chemical warfare threats during Operation Desert Storm. While this was largely considered by many as a political debate, it indeed drove numerous data calls, briefings, information papers, and close coordination among the Command's Pentagon staff, the Medical Chemical and Medical Biological Research Program offices and USAMMDA to keep our proponents informed and educated on important technological and readiness issues.

The final impact of the Rockefeller debates is not yet known. However, it is absolutely certain that products, which the FDA has neither approved nor licensed for our specific military needs, will never again be viewed as meeting readiness goals. As a positive step, the USAMMDA has now realigned its focus on product development that culminates in FDA approval. Our charge is to recognize that, perhaps, because of the nature of the threat and our inability to study the effectiveness of certain products in humans, applications to the FDA may require precedent-setting and creative approaches to navigate through the regulatory maze - and then act accordingly; this we are doing for Soldiers, Sailors, Airmen, and Marines.

As is human nature, these many changes during 1994 represented real threats to our "comfort level," and we can be proud of the fact that we emerged in remarkably good spirits, poised for continued, future success, and even more committed and focused on our core contribution to the Army Medical Department (AMEDD) and our Nation's warfighters. Part of the positive outcome is due to our recognition that the events of 1994 were mere signals of "more to come." These signals prompted several management initiatives we considered crucial for long- term medical materiel development success and responsiveness to the warfighters.

Led by USAMMDA and in collaboration with the Research Area Directors, the past year witnessed a complete reengineering of the Milestone 0 process in the Command. For the first time in the history of Army medical R&D, the leading organizations in materiel acquisition, including not only USAMMDA but also Research Area Directors,

the Combat Developer, and the AMEDD Logistician, are now defining medical materiel concepts much earlier to ensure that we focus investments on the highest priority, highest payoff medical systems for the AMEDD and the warfighters.

Customer focus continued to be an intense management objective for USAMMDA throughout 1994. This year, we successfully shifted the proponency of our product prioritization process, the Mission Area Materiel Plan (MAMP), to the medical Combat Developer - the warfighter's representative. It is now that office which predominantly guides the acceleration or deferral of advanced development projects, lending renewed credibility and utility to the AMEDD's Plan.

In turn, USAMMDA's obligation to the warfighters and to the AMEDD must be to concentrate limited resources on their highest priority needs. We were successful in executing our business plans efficiently and accomplished much this year in the development of the AMEDD's highest priority products.

For instance, in preliminary human studies, our Pharmaceutical Systems Division found the two leading malaria prophylactic drugs, WR238,605 and Azithromycin, to be safe and effective. These data will provide the foundation for further studies needed for FDA approval. A further accomplishment in our battle against malaria was the launching by our Biological Systems Division of a major study in Thailand to demonstrate the safety and efficacy of the malaria vaccine, SPf66.

Other important product accomplishments included the first-ever demonstration of human efficacy of the biological defense product, Cell-culture Derived Vaccinia (smallpox) vaccine and the finding of significant efficacy (i.e., 82%) of the Whole Cell Plus B Subunit Cholera Vaccine against that serious diarrheal disease. These accomplishments are key to the eventual application and licensure of these products by the FDA and their fielding.

We are also pleased with our success in acquiring an industry partner having the desire and capability to complete FDA-required studies on Hypertonic Saline Dextran. This product will make a significant contribution to the medic's ability to administer life-saving fluids to battlefield casualties.

After months of intense scientific collaboration and planning, USAMMDA filed a preliminary New Drug Application (NDA) with the FDA for their review and approval of the Nerve Agent Pretreatment, Pyridostigmine Bromide. Filing the NDA on Pyridostigmine was precedent-setting, requiring innovation in regulatory strategies to facilitate FDA acceptance of the NDA. Early feedback from the FDA was promising.

During the Spring of 1994, our Applied Medical Systems Division engaged in building full-scale mock-ups for evaluation of three candidate configurations of a new AMEDD concept, the Armored Ambulance. Through this accomplishment, the USAMMDA and the U.S. Army Medical Research and Materiel Command

demonstrated, yet again, our resolve in supporting the Combat Developer responsively with high-quality products.

Beyond the MAMP, USAMMDA continued to make dramatic changes in our core philosophies of fiscal and product management, empowering Product Managers to succeed. For instance, for the first time ever, USAMMDA developed a 3-year strategic planning process that enables efficient trade-off analyses for cost, schedule, and performance. This business tool is now part of the Reengineered USAMMDA - a USAMMDA that provides more and better tools to its product managers to enable success for the benefit of Soldiers, Sailors, Airmen, and Marines.

Another essential business tool provided to the product managers this year was total control and responsibility for managing their own checkbook. Each manager now has the responsibility to make execution decisions, maintain accountability of fiscal resources, and apply those resources to the highest payoff objectives in their Business Plans. This authority continues earlier management initiatives in USAMMDA that gave product managers full authority and responsibility for making "best buy" decisions from industry, academia, and the Command's technology base laboratories.

While changes and challenges were many during 1994, we refused to ignore the inevitable, even greater changes coming in the years ahead. Instead of shrinking away from these many challenges, we chose to confront them now to ensure that a vision of Quality, Integrity, and Accountability in Medical Materiel Development can be achieved.

As USAMMDA enters 1995 - and our second decade - we are in a remarkably sound position to "rightsize" appropriately, redefine and execute our mission efficiently, and account for successes - and failures - accurately and precisely. In so doing, USAMMDA will be able to meet our obligations to the warfighters to deliver quality medical products - earlier than promised, more cost-effectively, and FDA-approved.

GEORGE E. LEWIS, JR.
Colonel, VC
Commanding

U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY

"Developing Quality Products for the Soldier," the motto of the U.S. Army Medical Materiel Development Activity (USAMMDA)[1], truly represents operations as the proponent for all medical materiel advanced development for the Department of Defense (DOD). The USAMMDA is a subordinate unit of the U.S. Army Medical Research and Materiel Command located at Fort Detrick, Frederick, Maryland. This unique organization manages and directs medical materiel advanced development, achieving U.S. Army and Joint Service materiel system objectives within performance, schedule, and cost objectives.

1. MISSION STATEMENT

USAMMDA's specific mission is to manage the execution of the development component of the Army Medical Department (AMEDD) medical materiel acquisition program to achieve Department of the Army and Joint Service materiel system performance, schedule, cost and logistic objectives. This includes responsibility for centralized planning, direction, control, management, and focus for the Medical Materiel Developer's Program; achieving the Army's unique and Joint Service operational performance, schedule, cost and logistics objectives for each system and subsystem; developing acquisition strategies and resource allocations; and coordinating Combat Developer (CBTDEV) and Trainer plans to ensure combat readiness and initial production capability.

2. GOAL

Establish the most effective and efficient military medical materiel development program in the world.

3. OBJECTIVES

- Measure and evaluate the product development process.

- Accelerate, streamline, and economize the product development process.

- Emphasize best buy/best value principles.

- Fully utilize USAMMDA Business Plans as the focal point of product development, communication, and management.

- Transfer management authority, responsibility, and credit to the lowest effective echelon.

- Equalize workloads.

- Foster continuous improvement.

QUALITY - INTEGRITY - ACCOUNTABILTY

4. ORGANIZATION[2]

The Commander directs program execution through three Project Management Divisions, and assures adequate support for the programs through the Project Management Support Division. The Project Management Divisions focus on three separate and distinct development technology areas: the Biological Systems Project Management Division (BSPMD), the Pharmaceutical Systems Project Management Division (PSPMD), and the Applied Medical Systems Project Management Division (AMSPMD). While the specific Project Management Divisions address issues related to product development, the Project Management Support Division (PMSD) provides centralized program-wide administrative, financial, contractual, and logistical support.

The Quality Assurance Office reports directly to the Commander. This office directly supports the Project Management Divisions by being responsible to the Product Managers for ensuring quality and acceptability of test data, control processes, manufacturing data, and regulatory documentation for submission to the FDA in support of product safety and effectiveness for liscensure and approval. The Quality Assurance personnel conduct protocol review and monitoring for current Good Clinical Practices (cGCP), provide oversight of a regulatory affairs documents contract, ensure regulatory compliance in the conduct of clinical trials, and monitor adherence to current Good Manufacturing Practices (cGMP) in the operation of manufacturing facilities associated with advanced development projects.

A brief description of Division/Office highlights their principal focus, military relevance and objectives:

a. **The Biological Systems Project Management Division (BSPMD)** manages the development and initial production of biological products to prevent casualties or loss of soldier effectiveness due to natural disease and biological warfare agents. These diseases may be naturally acquired as a result of close contact conditions, contaminated environment, biting insects, or acquired by deliberate enemy exposure of troops to aerosols of biological agents including toxins. Product Managers exploit domestic and foreign medical technology to remedy deficiencies identified by the CBTDEV and assess research project outcomes for their application to disease protective measures.

(1) Reducing the impact of disease on operations will contribute significantly to soldier effectiveness. Casualties from disease have been a major cause of hospital admissions and ineffectiveness on the battlefield. Figures for admission for soldiers during a year in Vietnam were as follows: disease - 70.6 percent; battle casualty - 15.6 percent; nonbattle injury - 13.8 percent.

(2) The BSPMD addresses requirements for effective preventive measures against diarrheal diseases, malaria, hepatitis, meningitis, insect transmitted viruses, toxins, hemorrhagic fevers, and other diseases of concern to the military. Methods to address these deficiencies include vaccines, immune globulins and insect repellents.

b. **The Pharmaceutical Systems Project Management Division (PSPMD)** manages the development and the initial production of drugs, related drug delivery systems such as autoinjectors and transdermal patches, resuscitative fluids, skin protectants and skin decontaminating products.

(1) U.S. military forces must be prepared to serve anywhere in the world. PSPMD develops products for fielding as preventive, protective, and therapeutic modalities for use against chemical warfare threats; certain endemic diseases and the treatment of combat casualties. The development of products against these threats will sustain the fighting force, save lives, and enhance a casualty's recovery and return to duty.

(2) The PSPMD's objective is to develop pharmaceuticals to be used for prophylaxis, immediate treatment and definitive treatment against a wide variety of naturally occurring diseases, or of chemical agents and combat injuries. These pharmaceuticals include those for pretreatment and for use following exposure to organophosphorus compounds, vesicants and cyanide, and those to protect or treat soldiers suffering from malaria, schistosomiasis and leishmaniasis. In addition, a topical skin protectant is undergoing development to protect the skin against the toxic effects of exposure to mustard and other percutaneous chemical threat agents. From a more conventional aspect, blood replacement fluids and improved antimicrobial skin dressings and microencapsulated antibiotics are under development.

c. **The Applied Medical Systems Project Management Division (AMSPMD)** plans, directs, and controls the materiel development of all assigned applied medical systems (medical devices and equipment). A testing laboratory, a fabrication shop, and a drafting/design office, provides the AMSPMD with an in-house capability to modify commercial items for military medical applications as well as the ability to design and fabricate concept prototypes. These assets, along with a skilled force of engineers, health care specialists, and acquisition professionals, comprise the most comprehensive program for the development and testing of field medical materiel within DOD.

(1) The development of lifesaving diagnostic and therapeutic devices provides military health care personnel with the best equipment for the treatment of combat casualties while simultaneously reducing the logistics burden. The development of vision corrective eyewear for field use and of devices for medical protection against chemical warfare agents and other military hazards offers clear benefit to soldiers on the modern battlefield.

(2) The AMSPMD's objective is to develop and support the acquisition of compact, lightweight, rugged medical and medical support equipment in response to the needs of the AMEDD and the Joint Services. The AMSPMD strives to ensure the timely fielding of new hardware and software by evaluating and exploiting new technologies in the areas of patient care and medical support. A listing of equipment that was evaluated and tests conducted by the AMSPMD can be found in Appendix C.

d. **The Project Management Support Division (PMSD)** provides a centralized program-wide administrative, Planning, Programming, Budgeting and Execution System (PPBES), as well as financial, contractual, and logistical support to the Project Management Divisions. This improves resource accountability for materiel development throughout the AMEDD. Successful accomplishment of the Project Management Divisions' programs is inextricably linked to PMSD's performance in the following areas: business planning and execution; information management mission area; operation of a fiscal program planning system (General Analysis/Priority System (GAPS)); oversight and operation of major support contracts; management of the Research, Development, and Acquisition (RDA) Mission Area Materiel Plan (MAMP); and program development and defense through the Concept Base Requirement System (CBRS) cycle. These responsibilities and capabilities enhance in-house and program wide fiscal performance. Integrated logistics support, MANPRINT planning, production contract preparation, and test schedule coordination support provide timely logistics management.

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[1] Appendix A provides a list of commonly used acronyms
[2] Appendix B provides an organization chart

PRODUCT DESCRIPTION, MAJOR ACCOMPLISHMENTS AND PROJECTIONS

Advanced development products are presented in this section according to their 1994 Medical RDA Mission Area Materiel Plan (MAMP) prioritization. The MAMP is a concerted effort to determine the relative value to a field commander of the various products for reducing morbidity and mortality. Predevelopment products anticipated to transition to advanced development in CY95 and for which project management documentation activities were conducted, are separately listed in MAMP-rank order. A list of supporting contracts, special products, and non-MAMP prioritized products follows the MAMP Prioritized Products List. A listing of all products, by technical divisions, can be found in Appendix E.

1. **MAMP Prioritized Products**:

a. **Advanced Development Products:**

(1) **Antimalarial Drug WR 238605 (WR)** is an 8-aminoquinoline derivative which has demonstrated antimalarial potential in preclinical studies. It is being developed as a replacement for primaquine for the prophylaxis and treatment of malaria.

- A Phase I rising single dose clinical safety study was completed in 2QCY94.

- A Phase I multi-dose pharmacokinetic/pharmacodynamic study was initiated in 3QCY94.

- A Phase IIa single dose clinical efficacy study was completed in 3QCY94.

- A joint Collaborative Research and Development Agreement (CRDA) has been negotiated with two multinational pharmaceutical firms and will be executed in 1QCY95 to continue the development of WR 238605. The use of a CRDA will accelerate the development of WR 238605 and reduce resource requirements for the government.

(2) **Antimalarial Drug, Azithromycin (WR)** is an azalide, a subclass of macrolide antibiotics, similar to erythromycin. It is a Food and Drug Administration (FDA) approved oral medication manufactured and marketed by Pfizer, Inc., for the treatment of respiratory tract infections. It has demonstrated antimalarial activity both in vitro and in vivo. The product is being developed as an alternative or replacement for doxycycline, prophylactic.

- A Milestone I IPR was conducted in 3QCY94, transitioning the drug to advanced development.

- Two Phase IIa clinical efficacy studies were completed in 4QCY94.

(3) **Cholera Whole Cell Plus B Subunit Vaccine (WR/SW/NV)** is a combination killed, whole bacterial cell and B cholera toxin subunit oral vaccine for prevention of diarrheal and systemic illness caused by Vibrio cholera infections. Field studies suggest that the B subunit also affords some protection against enterotoxigenic Escherichia coli (ETEC), a common cause of diarrheal disease. The vaccine is being tested against both indications in collaboration with the Naval Medical Research Institute (NMRI).

- A large placebo-controlled efficacy field trial in 20,872 volunteers began in Pampas de San Juan in Lima Peru, in November 1993. There was active and passive surveillance for diarrheal disease throughout the past year. In the cholera season, there were 3-5 confirmed cholera cases per week in the study area. A booster dose was administered one year later. Surveillance is continuing; the code will be broken after this year's cholera season.

- A separate efficacy study was performed in 1,379 Peruvian military volunteers. Attack rates of 19.6 per 1,000 were detected in the placebo group and 2.8 per 1,000 in the vaccine group, an efficacy rate of 85 percent for the first 4 months after vaccination.

(4) **Hypertonic Saline Dextran (LR/TP)** is a small-volume resuscitative fluid suitable for rapid field administration that can be used to stabilize hypovolemic shock casualties.

- A CRDA was executed with Trauma Products, Inc. (TPI) in 4QCY94 which will allow the continued development of HSD.

- Data from the original New Drug Application (NDA) which was not approved by the FDA is being reanalyzed.

(5) **Malaria SPf66 Blood Stage Vaccine (WR/SL)** is a product based on a Columbian vaccine which consists of three peptides derived from two merozoite proteins and one circumsporozoite protein of Plasmodium falciparum. In preparation for clinical studies, the vaccine was synthesized by a rapid solid phase procedure in accordance with current Good Manufacturing Practices (cGMP).

- Phase I clinical studies in Thailand involving naive, semi-immune and immune adults; and children ages 2-15 demonstrated that the vaccine was safe and immunogenic. A Phase II study initiated in FY93 enrolled over 1200 Karen children. All received three doses of either the vaccine or placebo.

(6) Clinical testing of a **Tick-Borne Encephalitis Virus Vaccine (TBE) (RD)** to compare the standard immunization schedule with an accelerated schedule is ongoing. However, the manufacturer of the vaccine has made a corporate decision not to submit

a Product License Application (PLA) with the FDA. Other options such as to seek licensure with a second commercial TBE vaccine or to independently produce a TBE vaccine, are being evaluated.

(7) **Antimalarial Drug, Halofantrine, Prophylactic (WR)** is a 9-phenanthrenemethanol compound being developed as an alternative prophylactic to chloroquine and mefloquine for prevention of multi-drug resistant Plasmodium falciparum malaria.

- A Phase I clinical study, evaluating the effect of diet on drug absorption was completed.

- Studies to examine cardiotoxicity associated with halofantrine administration were initiated at Georgetown University.

(8) The **Intraosseous Infusion Device (LR)** is a product that will allow access to the intraosseous space for the infusion of resuscitative fluids when peripheral vascular access is unobtainable. It is intended to be used on the battlefield for the severely traumatized casualty in profound shock.

- The market investigation revealed two companies which manufacture a needle that may meet the mission need. Both devices have FDA approval.

(9) **Detoxified LPS-OMP Meningococcal Group B Vaccine (WR)** consists of noncovalent complexes of purified meningococcal outer membrane proteins (OMP) and alkaline detoxified meningococcal lipopolysaccharide (LPS). One lot of this vaccine was manufactured at WRAIR.

(10) **Hantaan M-S (Vaccinia Vectored) Vaccine (RD/SL)** is a live vaccine for military personnel being deployed to regions in which this agent is endemic. The vaccine was engineered at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) by inserting the genes which code for Korean Hemorrhagic Fever (KHF) or Hantaan antigens into the live vaccinia virus carrier (smallpox vaccine). The resulting recombinant vaccine was manufactured by the Salk Institute and was shown to elicit antibodies against both vaccinia and Hantaan Viruses.

- The Investigational New Drug Application (IND) was accepted by the FDA for clinical trials 4QCY93.

- The vaccine has been shown to be safe and immunogenic in those volunteers that develop a pox lesion.

(11) **Rift Valley Fever, Live Vaccine (RD/SL)** is an improved vaccine which will provide immunity with a single dose rather than the three doses required for the current inactivated vaccine. The vaccine will provide greater protection in a shorter amount of time to service members operating in geographic areas where there is high risk of infection with Rift Valley Fever.

- Studies of varying vaccine doses were initiated in CY94.

(12) **Tularemia Live Vaccine (RD/SL)** is an attenuated vaccine for military personnel being deployed to an area where there is a potential threat use of Francisella tularensis. Several lots of vaccine were prepared at the Salk Institute.

- Clinical trials to establish lot consistency (for licensure) were completed at Johns Hopkins University and USAMRIID.

(13) Inactivated **Hepatitis A (WR/SK)** vaccines produced by SmithKline Beecham have been tested to determine safety and immunogenicity.

- A Product License Application filed in CY93 for the Inactivated Hepatitis A (WS/SK) vaccine produced by SmithKline Beecham is still being reviewed by the FDA. In CY94, the FDA requested supplemental information on subclinical cases in the Phase 3 Hepatitis A Thai children study. The data provided to the FDA are being reviewed.

(14) **Argentine Hemorrhagic Fever Live Vaccine (AHF) (RD/SL)** is an attenuated vaccine for military personnel being deployed to areas where AHF is endemic. The vaccine was prepared by growing the virus in fetal rhesus monkey lung cells in a collaborative effort between USAMRIID and the Salk Institute.

- A Phase III field trial in approximately 6500 at-risk Argentine volunteers demonstrated that the vaccine was highly efficacious. Manufacturing consistency lot studies are in progress at USAMRIID.

(15) **Cholera Whole Cell Plus B Subunit Vaccine (ETEC Indication) (WR/SW/NV)** is the same vaccine used to protect against cholera. There is cross protection against entertoxigenic Escherichia coli (ETEC) by the B subunit of the cholera toxin. The vaccine is being tested against both cholera and ETEC in collaboration with the Naval Medical Research Institute (NMRI).

- A large placebo-controlled field trial in 20,872 volunteers was initiated in Pampas de San Juan in Lima, Peru, in November 1993. There was active and passive surveillance for diarrheal disease throughout the following year. A booster dose was administered at 1 year. Surveillance and sample collection and evaluation continue.

(16) **Nerve Agent Pretreatment Pyridostigmine (IC/WR)** is a cholinesterase-inhibiting drug that is a pretreatment effective against nerve-agent lethality when used in conjunction with antidotal atropine and 2-pralidoxime chloride.

- An NDA was submitted to the FDA in 1QCY94.

- A clinical study was initiated to study the tolerance of females and low weight individuals to doctrinal doses of pyridostigmine.

- A rodent preclinical study to investigate synergism between DEET, permethrin and pyridostigmine was initiated in 3QCY94.

- The Chemistry, Manufacturing and Control (CMC) Section of the NDA is in preparation.

(17) **Enterotoxigenic E. coli Plus B Subunit Vaccine (WR/SW/NV)** is a combination of killed whole bacteria expressing different colonization factor antigens plus cholera toxin B subunit prepared by recombinant biotechnology. The cholera toxin B subunit vaccine offers cross protection against the E. coli enterotoxin. The vaccine was manufactured by the Swedish Bacteriological Laboratories under a CRDA.

- A Phase 1 clinical trial showed the vaccine to be safe and immunogenic. The manufacturer changed formulation of the vaccine, and a second Phase 1 trial determined this vaccine was also safe. Immunogenicity testing is pending.

- Field sites for efficacy trials with the vaccine have been chosen.

(18) **Smallpox Live Vaccine (RD/SL)** is a new, cell culture produced animal poxvirus (vaccinia) that is free of bacteria presently found in the calf lymph vaccine.

- The IND was filed 1QCY93. A Phase I dose escalation study, completed in 3QCY93, suggested that lesion formation may be required to obtain an immunologic response.

-A Phase II study was completed 3QCY94 in 100 volunteers at Brooke Army Medical Center, Fort Sam Houston. The vaccine candidate was administered either intradermally (ID) or intramuscularly (IM) and neutralizing antibody titers to vaccinia were compared to titers in volunteers administered the licensed Wyeth Vaccine via scarification. Only three volunteers were given the candidate vaccine by scarification . By the ID route, the candidate vaccine was immunogenic in those volunteers that developed a pox lesion. Two of the three volunteers given the vaccine by scarification had titers equal to the Wyeth vaccine.

(19) **E. coli Vectored S. flexneri Shigella Vaccine (WR/SL/IS)** is an oral vaccine produced by inserting genes for S. flexneri antigens into an Escherichia coli vector. This bioengineered vaccine was developed at WRAIR, produced at Salk, and tested at the University of Maryland Vaccine Testing Facility, and in Israel. New lots of vaccine are being produced at the WRAIR cGMP facility at Forest Glen.

- A 2-year, 3-arm Phase II expanded study was initiated 1QCY93 in Israel. Preliminary results suggest that the S. sonnei vaccine protects against S. sonnei shigellosis. Since there has been no flexneri 2a disease in the vaccinated cohort, the only data resulting from this effort was additional safety data. The reactogenicity rate, approximately 6%, was not problematic for the Israeli soldiers involved in vigorous field activity.

(20) **C. botulinum Type F Toxoid (PC/RD)**, a formalin inactivated monovalent toxin, adsorbed to alhydrogel under cGMP, was produced at the Center for Applied Microbiology Research (CAMR) . The toxoid was safe and immunogenic at a 10 µg (microgram) dose in a Phase I clinical study performed at USAMRIID.

- Improved immunization schedules are being evaluated at the University of Maryland Vaccine Testing Facility.

(21) **Schistosome Topical Antipenetrant (WR/NV/MI)** is a niclosamide based skin lotion that is designed to prevent the penetration of free swimming Schistosoma larva.

- The Schistosomiasis Scientific Steering Committee (SSC) recommended, based on the results of three clinical trials, that an additional clinical trial be conducted in the field, using schistosome naive populations, to conclusively demonstrate efficacy in humans. Efforts to locate such a naive population were not successful. In 1QCY95, the SSC will discuss the feasibility of conducting this kind of trial and whether there are alternatives which could be considered.

(22) **C. botulinum Toxoid, Pentavalent (Types A,B,C,D,E) (SL/PC/MD)** will be produced and incorporated into a polyvalent vaccine to protect military personnel. These toxoids will be used for military personnel deployed to areas where there is potential threat use of Clostridium botulinum toxins. To prepare toxoids, the toxins are purified from C. botulinum cultures and inactivated with formalin. The toxins will be concentrated by ultrafiltration and purified by ion exchange chromatography prior to producing toxoids. The toxoids will be tested separately, and eventually together, for their ability to elicit toxin neutralizing antibodies in humans.

- Production of Types C & E have been completed at CAMR. Type D Toxoid transitioned from development into the pharmaceutical production suite at CAMR.

- Types A and B toxin were produced by the Salk Institute's Government Services Division in a renovated production facility within USAMRIID. Type B toxoid is produced by a procedure which includes column chromatography.

(23) **Topical Skin Protectant (TSP) (IC/IA/BT)** is a perfluorinated formulation, which, when spread on the skin, forms a thin and breathable film surface capable of significant protection against percutaneous penetration of chemical and a limited number of biological warfare agents. Doctrinally, TSP is to be used as an adjunct to mission-oriented protective posture gear, not as a replacement. Use of the TSP enhances the effectiveness of fielded skin decontaminating systems.

- The analytical methods for specifications were standardized; initial TSP specifications were achieved. Clinical supplies were prepared in accordance with current Good Manufacturing Practices.

- Animal efficacy testing, completed in 3QCY94, showed the TSP was effective against the percutaneous hazard of tear gas (CS) and T-2 mycotoxin.

- An Investigational New Drug Application was submitted to the FDA in 4QCY94.

(24) **Chikungunya Live Vaccine (RD/SL)** is an attenuated product produced by growing the virus in cultured human lung cells at USAMRIID. The Salk Institute produced the investigational lots of virus vaccine.

- Clinical trials involving 120 individuals to date continue to demonstrate that the live vaccine is safe and immunogenic.

(25) **Campylobacter Vaccine (NV)** is a killed, whole cell, adjuvanted oral vaccine for prevention of diarrheal and systemic illness caused by gram-negative bacteria of the genus Campylobacter.

- The adjuvant to be mixed with this vaccine, a heat labile toxin of E. coli has been purchased from the Swiss Serum and Vaccine Institute. Dose-seeking and safety testing in clinical trials with the Whole Cell/Recombinant B Subunit (WC/RBS) Cholera Vaccine has been completed. Determination of the effect of the adjuvant on immune response to the vaccine is pending.

- Manufacture of a pilot lot of campylobacter vaccine has been completed and assembly of an IND is underway.

(26) **Shigella Sonnei Vaccine (WR)** is an O-specific polysaccharide of the bacteria covalently bound to exoprotein A of P. aeroginosa to form conjugates. This vaccine is to be administered parenterally.

(27) The **Self-Contained Ventilator (AL/IC/HS)** is a battery powered ventilator designed to pump filtered ambient air or bottled gas and sustain casualty respiration even in a chemical environment. This ventilator will be used at levels I/II.

- The requirement for a Cost and Operational Effectiveness Analysis (COEA) document was waived by the USAMEDDC&S. The U.S. Army Institute of Chemical Defense performed laboratory evaluations of two candidate ventilators. The U.S. Army Aeromedical Research Laboratory began their pre-test Helicopter Airworthy Evaluation activities of candidate ventilators in 4QCY94.

(28) **Antileishmanial Drug WR 6026 (WR/IA)** is an 8-aminoquinoline derivative developed as an oral treatment for visceral leishmaniasis.

- A Phase II efficacy trial has been designed and will be conducted in Brazil pending U.S. and Brazilian government approval. A mutagenicity study is being conducted and will conclude in 1QCY95.

- A joint CRDA has been negotiated with two multinational pharmaceutical companies. The CRDA will enable acceleration of the development of this drug while decreasing the financial investment by the government.

(29) The **Medical/Dental Filmless Imaging System (ID)** is a system for the filmless capture and display of diagnostic images. The system is aimed at the elimination of film, film processors, and chemicals from the field by obtaining the radiographic information in a digital format.

- A prototype dental imager based on charged coupled device technology was evaluated by users in Haiti in December 1994. The preliminary results were very promising. A second system, based on amorphous crystal technology, is being readied for field evaluation. Both of these systems are currently under development by commercial companies and will be available for NDI procurement by the time requirements have been finalized.

(30) **C. botulinum Type G (PC)** toxin was produced at CAMR under non-cGMP conditions; 34 mg of the toxin were used to vaccinate horses to produce Botulism F(ab')2 Antitoxin Heptavalent (Equine Derived). Small scale fermentation of the selected strain of Botulinum Type G was completed at CAMR under non-cGMP conditions. Purification procedures were completed for two of the three purification columns required for the final product.

(31) **Nerve Agent Antidote System (NAAS), HI-6 (IC/WR/DC)** is a replacement for the fielded Nerve Agent Antidote Kit or the Multichambered Autoinjector. The NAAS will be a service member carried item for self-aid and buddy-aid that will require NDA approval by the FDA. The Nerve Agent Antidote System contains atropine and an improved acetylcholinesterase reactivator, HI-6. Animal data suggest

that this regimen will provide improved efficacy against the lethal effects of all nerve agents and may reduce the immediate impact of nerve agent attack on combat effectiveness or accelerate the return to combat effectiveness of units exposed to nerve agent.

- A pre-IND meeting was held with the FDA 4QCY94.

- Toxicology studies conducted during CY94 determined that HI-6 is non-mutagenic both in vitro and in vivo.

- Several additional toxicology studies, a metabolism study, as well as studies on the physico-chemical properties of HI-6, were completed.

- A major comparative efficacy study was initiated to demonstrate efficacy in non-human primates.

(32) **Q Fever CMR Extract Vaccine (RD/SL)** is a purified formalin and gamma irradiation inactivated vaccine prepared at the Salk Institute. The intracellular bacteria are harvested from the infected yolk sacs of embryonated chicken eggs. Extraction with chloroform-methanol (devised at the USAMRIID) is believed to lessen the reactogenicity of the vaccine.

- Expanded clinical trials for a 100 µg dose in 60 volunteers at the Center for Vaccine Development at the University of Maryland showed the vaccine is safe. Plans are underway to determine the reactogenicity of the vaccine in known skin test positive individuals.

- Monkeys have been immunized with the vaccine and will be challenged by an aerosol route at 6 months. We plan to use these data in lieu of data from a field study in our license application.

(33) **Nerve Agent Antidote, Multichambered Autoinjector (MA)** is a single-barreled, dual-chambered autoinjector which injects the nerve agent antidotes, atropine and pralidoxime chloride, through a single needle.

- A contract was awarded in 1QCY94 to complete development. Prototype MAs were produced for MIL-STD 810E and stability testing. A clinical protocol for a pivotal bioequivalence study was written and approved by the Human Subjects Research Review Board (HSRRB).

(34) The **Field Medical Oxygen Generating and Distribution System** is an on-site, lightweight medical oxygen generating and distribution system which provides both bedside and cylinder-refill oxygen capabilities within Table of Organization and

Equipment hospitals and medical logistics organizations. The system is designed to provide greater mobility and operational flexibility and to reduce the logistics burden of medical grade oxygen resupply.

- Three Low Rate Initial Production modules were delivered to the Operational test site 1 August 1994. A fire occurred in one cylinder filling module during testing. The units were returned to the manufacturer for repair and modification based on recommendation by a NASA oxygen fire analysis team.

(35) **Botulism Immune Globulin $F(ab')_2$ Heptavalent Equine (OT/SL)** is an equine immunoglobulin prepared by fractionation of horse plasma from hyperimmune animals to treat personnel exhibiting symptoms of botulism. The plasma is treated with pepsin to cleave the Fc portion of the antibody molecule. The F(ab')2 fragments are isolated by affinity chromatography. Organon Teknika is the Contractor which maintains, harvests, and processes the horse plasma to final product. The horses have been immunized and plasma is being collected. Validation of the facility is underway.

(36) **Botulism Immune Globulin (Human) (RD)** is a human immunoglobulin prepared by fractionation of plasma from volunteers hyperimmunized with pentavalent botulinum toxoid.

- Lots 1A and 1B will be transitioned for use by intravenous administration under a treatment protocol with informed consent.

- Lot 2A, which was positive for endotoxin, will be transitioned for use by intramuscular injection under a treatment protocol with informed consent.

- Lot 2B was positive for Human Immunodeficiency Virus (HIV) by Enzyme Linked Immunosorbent Assay (ELISA), but negative by Western Blot analyses. This lot will be used in passive transfer challenge studies in animals to produce a surrogate efficacy study for licensure of the pentavalent botulinum toxoid.

(37) The **Armored Ambulance** is a collaborative effort to design a medical interior for an existing armored vehicle which will replace the M113 armored ambulance. Emphasis will be placed on new medical technologies for improved patient treatment and care during evacuation.

- Full size wooden mock-ups of the stretch M577 Armored Command Post vehicle, the M992 Field Artillery Ammunition Support Vehicle, and the new Bradley-based Command and Control Vehicle (C2V) were assessed by user representatives from the USAMEDDC&S. A clear preference was indicated for the C2V vehicle and for the all-manual Air Force litter system with secondary preference for a commercial electro-mechanical lift system.

- Refinement on the interior arrangement of litter systems and medical equipment in the C2V is now underway.

(38) The **Liquid Oxygen Production, Storage, and Distribution System (LOPSDS)** is a transportable, centralized generating and storage system which produces liquid oxygen (LOX) in a Theater of Operations. Bulk tanks (100 to 400 gallons) are used to transport LOX product to hospitals where it is vaporized into gaseous oxygen for distribution to operating rooms and patient wards or to fill pressurized oxygen cylinders.

- Commercial systems are available that produce LOX from ambient air and may satisfy battlefield requirements for medical oxygen. The Life Cycle Cost Assessment for LOPSDS was finalized and incorporated into the draft Operational Requirements Document (ORD). A detailed system requirements plan was staffed and a Joint Working Group (JWG) convened to discuss issues associated with system operation, maintenance, training, and support. The LOPSDS Mission Needs Statement (MNS) was approved by Headquarters, Department of the Army and the draft ORD was submitted to the U.S. Army Training and Doctrine Command for approval. An initial draft Basis of Issue Plan Feeder Data and Qualitative and Quantitative Personnel Requirements Information was prepared.

(39) The **Field Triage Light (BL)** is a portable light, powered by rechargeable batteries, for illumination at triage sites and for emergency lighting. Batteries will provide power to a 15 watt fluorescent light in excess of eight hours, or to an incandescent light for a lesser time.

- A market investigation was completed; potential modifiable NDI lights were identified; samples will be evaluated. In-house efforts have focused on incorporating state-of-the-art rechargeable batteries, lightweight electronics, and high efficiency lighting to produce a prototype that optimizes light output, battery operation, weight, and size.

(40) The **Field Anesthesia Machine (FAM)** is a compact, rugged anesthesia system for the delivery of the volatile anesthetic agent forane. The FAM will be an FDA approved upgrade to the Ohmeda Model 885A field anesthesia machine which is not approved by the FDA for use in CONUS hospitals.

- A draft RFP was developed and staffed. Three Joint Services Working Group meetings were conducted to discuss the RFP and identify essential characteristics for the FAM.

(41) The **Low Temperature Sterilizing System (SI)** effects rapid sterilization of surgical instruments by the use of a packaged dry-powdered chemical sterilant that is added to potable water which forms a peracetic acid solution. This chemical sterilant

may be used up to eight hours and is suited to sterile processing of immersible instruments and accessories.

- The contractor for this phase II Small Business Innovation Research (SBIR) contract is completing final technical testing to satisfy regulatory requirements for submission to the FDA and the Environmental Protection Agency (EPA) for approval to market. This new product will be more effective and more environmentally-friendly than the currently fielded glutaraldehyde-based chemical sterilant.

(42) The **Field X-ray Table** is a lightweight platform on which to position patients for medical imaging in the field. It weighs less than 125 pounds and has a "buckey system" that allows patient imaging in either the horizontal or vertical position. A table identified from an extensive market investigation was procured and modified to meet CBTDEV requirements.

- The unit underwent user evaluation by the AMEDD Test Board and was well received by the users. A product specification was developed and sent to the CBTDEV with the recommendation that it be standardized and procured as a modified NDI item.

(43) The **Lightweight X-ray Film Development Kit (BL)** is a series of fabric bags suspended on a lightweight frame to hold chemical solutions for x-ray film development under austere or emergency conditions. When not in use, the kit can be disassembled and compressed into a package of minimum size and weight.

- The final product underwent Technical Testing at USAMMDA and User Testing at the USAMEDDC&S. A level three TDP was forwarded to USAMMA for standardization and procurement.

(44) The **Diagnostic Kit for Biological Warfare Agents (NLI/NM/RD)** is a rapid system for use in a field medical laboratory to confirm exposure to biological warfare agents from clinical samples.

- Several JWGs were held to bring together Army and Navy laboratory scientists, the Logistician and the CBTDEV. This program has an approved MNS and the Navy, Air Force, and Marine Corps have recommended a Joint Potential Designator of "Joint Interest." A correspondence Milestone 0 package has been assembled. Collaboration is ongoing with Edgewood Research, Development and Engineering Center (ERDEC) to provide insight on related DOD technology.

(45) The **Thawed Blood Processing System (LR)** is a fully integrated system that will remove the glycerol solution (used to preserve blood cells) prior to administration to patients. The system will be automated to allow rapid blood cell processing with minimal manpower requirements. The system will be closed to prevent contamination of the blood during processing and will support increased shelf-life.

- The contract for phase II of the SBIR program is anticipated in February 1995. The objectives for phase II are to develop a second generation prototype in the first year and an advanced, third generation prototype in the second year. The primary requirements for the advanced prototype are to be fully automated, to deglycerolize thawed blood in less than 30 minutes, and to attain a three-week shelf-life of the output blood.

(46) **The Microencapsulated Antibiotic, Ampicillin, Dental (MEAA)(ID/SR)** is an antibiotic delivery system designed for single dose, direct wound site application by medical personnel at the time of debridement of maxillofacial injuries. It is capable of maintaining antibiotic concentrations at high levels at the wound site while producing systemic concentrations that are much lower than with conventional treatments.

- Studies were completed which demonstrated that MEAA induced fewer hypersensitivity reactions in an animal model than did an equivalent dose of free ampicillin.

- An RFP seeking a developmental contractor for the MEAA was released in 4QCY94.

(47) The **Lightweight Motor Blower (LWMB)** is a small, battery operated optional blower which will provide filtered, ambient air to a patient being transported inside the Wrap, Patient, Chemical Protective (NSN 6530-01-383-6260) in hot climatic conditions.

- The ERDEC has an NDI acquisition program in progress to obtain a LWMB which will provide filtered air for U.S. Army aircrews who must fly in contaminated environments wearing the M43A1E1 (future M48 and M49) Aircrew Chemical-Biological Protective Mask. The ERDEC conducted initial technical testing of blowers submitted by five companies which were provided feedback on the test results for their candidate. Four companies corrected identified deficiencies and resubmitted blowers for final technical testing. Successful candidates will undergo Pre-production Qualification Testing next calendar year. Information about the ERDEC program was obtained, and the LWMB specifications were reviewed with the Medical Combat Developer. It was determined that the blower specifications may satisfy the AMEDD need for an operational blower. Monitoring of the LWMB program at ERDEC continues.

(48) An IPR conducted in CY94 terminated the advanced development of the **Human Immunodeficiency Virus (HIV)** recombinant vaccine, Retrovirus Envelope Vaccine, GP160, Therapeutic (WR/MG), and returned the product to tech base for further evaluation and determination of the best construct for use in a vaccine.

b. **Predevelopment Products:**

(1) **Ricin Toxoid Vaccine (RD/SL)** is a formalin inactivated toxin, adsorbed to alhydrogel under cGMP by the Salk Institute. The vaccine was demonstrated to be safe and immunogenic in rodent preclinical studies performed CY93/94.

(2) **Improved Anthrax Vaccine (RD/SL)** was produced in pilot lots by the U.S. Army Medical Research Institute of Infectious Diseases. Product definition and scale-up production procedures are scheduled for completion 3QCY95.

(3) **Recombinant Vaccine for Hemorrhagic Fever Renal Syndrome (PUUMALA) (RD)** is a Vaccinia-vectored vaccine to protect against Hemorrhagic Fever Renal Syndrome (HFRS). A Milestone I In-Process Review and vaccine production are scheduled for late CY95.

(4) **Staph Enterotoxin B (SEB)Toxoid, Microencapsulated (WR/RI)** produced by formaldehyde inactivating SEB is being produced in pilot lots at the WRAIR cGMP facility at Forest Glen.

(5) **Cyanide Pretreatment (CP)WR 242511(WR/IC)**, a pre-transition product, will be an oral formulation which will provide protection against cyanide poisoning. The active ingredient will be a methemoglobin former of the 8-aminoquinoline class. Animal data suggest that this regimen will provide protection against the lethal effects of 2 LD50 of cyanide. Currently, there is no FDA approved pretreatment for cyanide exposure. A Milestone 0 decision advanced the CP to the Concept Evaluation and Definition in 2QCY94. Actions to conduct a Milestone I were initiated.

(6) **Topical Antileishmanial Drug, Paromomycin (WR279396)**, a pre-transition product, is a topically applied cream for the treatment of cutaneous leishmaniasis. Currently, there is no FDA approved treatment for cutaneous leishmaniasis in the USA. The present treatment, pentostam, is administered under IND, intravenously, and requires extensive treatment in a hospital setting. A topical treatment could be used in the field and would eliminate loss of duty days and very high cost of hospital treatment.

- Additional preclinical toxicology studies must be performed prior to Milestone 0.

(7) **Antimalarial Drug, Arteether (WR)**, a pre-transition product, is an antimalarial drug that is a derivative of the Chinese herbal remedy Qinghaosu. It has been shown to inactivate malaria parasites in cell cultures and animal model test systems. It is intended as an expedient, intramuscularly injected treatment for severe

and complicated multi-drug resistant malaria; without the availability of this drug, fatality rates among nonimmune adults could exceed ten percent. A Milestone 0 is scheduled for 1QCY95.

(8) **Leishmania Skin Test (WR)** Phase 1 clinical trials using GMP produced antigen are scheduled for completion 3QCY95, and the product will be transitioned to advanced development 4QCY95 for Phase 2 trials.

2. **Production and Deployment Support:**

a. The **Aerosol, Generator, Ultra Low Volume, Electric (AGULVE) (BL)** is a lightweight aerosol dispersal unit for pesticide application operations. The unit is comprised of a spray head and pump which is powered from a vehicle's electric power supply.

- Distribution Plan for 24 AGULVEs was forwarded to the U.S. Army Aviation and Troop Command (ATCOM). The U.S. Army Medical Materiel Agency (USAMMA) has agreed to provide funds to ATCOM. Assistance will be provided to ATCOM as needed during procurement and fielding.

b. **M40 Chemical-Biological (CB) Protective Mask Vision Correction (Materiel Change)** is a vision-correction device using the Ballistic Laser Protective Spectacle prescription lens carrier (PLC) and is internally mounted on the M40 CB protective mask. The prescription lens carrier is mounted in the frame component of this eyewear.

- System development and testing have been completed, and the Vision Correction Mounting System (VCMS) has been approved for use. Actions were initiated to transition the VCMS to the Army Medical Department for standardization. A low rate initial production of 75,000 systems began.

c. The **Sprayer, Pesticide, Electric, Liquid (SPEL) (BL)** is a lightweight hydraulic sprayer for the application of pesticides to insect breeding areas. This unit is comprised of a hand-held sprayer, a 20-gallon storage tank, and a pump which operates from the electric power supply of the transporting vehicle.

- Distribution Plan for eight SPELs was forwarded to ATCOM. USAMMA has agreed to provide funds to ATCOM. Assistance will be provided to ATCOM as needed during procurement and fielding.

d. The **Water Quality Analysis Set - Preventive Medicine (BL)** utilizes test-strip and drop-count titration technology to determine if field water supplies meet established standards for arsenic, cyanide, chloride, magnesium, and sulfate in potable water.

- Commercial kits, reagents, and supplies are available for expanding an existing medical capability. Updated technical purchase specifications were provided to the Medical Assemblage, Design, and Development Branch, USAMEDDC&S, to assist in their mission in defining the water quality analysis set assemblages.

e. The **X-ray System, Dental, Miniature (ID)** is a small, lightweight, hand-held dental x-ray system for field use. It is battery operated and suitable for use with self-developing film or digital imager.

- A product specification, a first article test protocol and a draft procurement package were developed and the product transitioned to USAMMA for NDI procurement. It is currently in the procurement cycle; a contract should be in place by the end of CY95.

f. **The Antimicrobial Dermal Dressing (ADD) (ID)** will be capable of providing sustained release of antimicrobial agents at the site of superficial dermal injury to prevent infection, enhance healing, and protect against the external environment. The ADD is being developed for the Special Operations Command (SOCOM).

- A customer test of a commercial ADD was conducted during 3QCY94.

3. **Contract Projects**:

a. **Salk Vaccine Production Facility** is a manufacturing facility dedicated exclusively to the development and production of investigational vaccines for clinical trials and diagnostic reagents under federal regulatory guidelines. The facility is managed by a delivery order contract for scheduling production of vaccines and reagents.

- The Salk Facility continues to perform tests to extend the shelf life of Vaccinia Immune Globulin (VIG) as a result of tasking from the Assistant Secretary of Defense for Health Affairs, and is responsible for receiving, inventorying, storing, potency testing, and shipping this extended date product as directed. The Facility also produced 18 additional bulk lots of botulinum A and B toxoids. They also evaluated and finalized a partial purification/concentration procedure for the botulinum A and B toxins. Human and horse serum specimens were tested using a standardized botulinum neutralization test, developed by the Salk Facility. Two lots of Ricin toxoids were prepared and preclinically tested. An additional lot of Plasmodium Falciparum Blood Stage Vaccine (SPf66) was formulated, packaged, and preclinically tested. Two lots of Argentine hemorrhagic fever vaccine were prepared, tested, and a data package assembled for submission to the FDA. Six additional lots of dengue vaccines were produced and preclinically tested. Diagnostic antigens and monoclonal antibodies continue to be produced for USAMRMC laboratories.

b. **University of Maryland Vaccine Testing Facility** evaluates vaccines in human safety, immunogenicity, and efficacy trials. The trials are done either on hospitalized volunteers in the 32-bed isolation ward or on outpatients. Each trial is performed under a specific task order and detailed protocol.

- The University of Maryland Vaccine Testing Facility continues to be an integral part of the vaccine testing program, testing both active advanced development products, and products in pre-development requiring human use studies.

- During the past year, a dosing and scheduling study of the botulinum toxoid type F was initiated .

- A protocol for an expanded safety study of the attenuated Chikungunya vaccine was approved, and recruitment of volunteers was initiated.

c. **South Florida Drug Research Corporation** conducts Phase I clinical studies on candidate pharmaceutical products. These studies evaluate the pharmacokinetics, pharmacodynamics, tolerated dose levels and associated side effects of each tested product. These studies are done in a 60 bed clinical facility or on outpatients. Each study is performed under a specific task order and detailed protocol. In CY94:

- A single dose safety study of Antimalarial Drug WR238605 was completed.

- A final report was delivered for the single dose study of Antimalarial Drug, Halofantrine Prophylactic.

- A study was initiated to evaluate the tolerance of females and low weight individuals to the doctrinal dose of pyridostigmine.

- A task order was initiated for a multi-dose study of the Antimalarial Drug, Halofantrine Prophylactic.

- Protocols were developed for two studies on the Topical Skin Protectant.

- A protocol was developed for a multi-dose study of the Antimalarial Drug WR238605.

d. The **University of Illinois at Chicago, Toxicology Laboratory** conducts preclinical toxicology studies on candidate pharmaceutical products. These Good Laboratory Practices (GLP) - compliant animal studies are required by the Food and Drug Administration to support Investigational New Drug Applications and New Drug Applications for pharmaceutical products. Each study is performed under a specific task order and in accordance with a detailed protocol. During CY94:

- One, two and four week segment II teratology range finding and in vitro mutagenicity studies on the anticyanide drugs WR242511 and WR269410 were conducted. Segment II teratology work on WR242511 was initiated.

- Thirteen week toxicity studies of the Antimalarial Drug WR238605 were completed in both rat and dog. Segment II teratology and in vitro mutagenicity work on WR 238605 continued. Protocols are being prepared for a pharmacokinetic study and for a 6-month study in the rat.

- A four week study of Antimalarial Drug Halofantrine, Prophylactic was conducted.

- One and four week studies and an in vitro mutagenicity study of the Nerve Agent Antidote System (HI-6) were completed.

- A wound irritation study on Microencapsulated Antibiotic, Ampicillin was conducted.

- A protocol was developed for a four week study of the Topical Antileishmanial Drug, Paromomycin.

- Segment II teratology and in vitro mutagenicity studies of the Antileishmanial Drug WR6026 were initiated.

4. **Special Projects**:

a. The **Convulsant Antidote Nerve Agent (CANA)** is a diazepam 10 mg autoinjector intended to prevent or abate convulsions and prevent or reduce brain injury associated with nerve agent poisoning. The CANA is a soldier-carried item to be used by buddy-aid in conjunction with the Mark I Nerve Agent Antidote Kit.

- The CANA was transitioned to Defense Personnel Support Center (DPSC) for Operations and Support.

- Survival Technology, Inc. (STI) will be qualified as a source for the manufacture of the CANA under an Industrial Base Maintenance Contract.

- USAMMDA continues to provide technical support to DPSC and STI in the production of CANA.

b. **Vaccinia Immune Globulin (VIG)** satisfies the DOD operational requirement to replace outdated stocks of VIG. It is used for potential vaccinia complications resulting from investigational vaccinia vectored vaccines, use of standard vaccinia as a smallpox vaccine, or to treat cases following offensive use of smallpox virus by

adversaries. The VIG manufacturer uses plasma from immunized volunteers to ensure a product that exhibits potency criteria required for a licensed product.

- The Alpha Therapeutic Corporation collected vaccinia immune plasma for two production runs of VIG. This plasma was sent to the Hyland Division, Baxter Healthcare Corporation, for manufacture of VIG.

- Approximately 6,000 vials of VIG were obtained from the first production run by Hyland.

c. Monitoring of **pre-development products requiring human use studies** continued. INDs and Phase I studies for several dengue vaccines and P. falciparum malaria sporozoite vaccines are on-going. A microencapsulated ETEC Vaccine was tested at the University of Maryland. An IND is being assembled for a Leishmania Skin Test which will be an immunological technique for screening of individuals suspected to be infected with Leishmania tropica.

d. The Greer Laboratories **Plague Vaccine** licensure, submitted 4QCY93, was approved by the FDA 3QCY94.

e. The **Aircrew Protective Mask, XM45, Vision Correction** supports some of the development aspects of new vision corrective eyewear for the XM45, such as optical fabrication support for eyewear lenses.

- The vision corrective insert continued to evolve into a design which will provide optimum soldier vision and which can be supported using AMEDD equipment and assets. The Chemical-Biological Defense Command program administratively transitioned to Engineering Development phase.

- A Soldier Enhancement Program (SEP) for infantry and armor versions of this protective mask (XM46 and XM47, respectively) was initiated. The SEP was accelerated to piggyback the projected advanced development schedule.

f. The **Electrochemical Ozone Generating Module (LT)** generates high concentrations of ozone from water and oxygen in air. Ozone is a very effective gaseous sterilant. When dissolved in water, it oxidizes organic molecules. The module could be retrofitted on an ethylene oxide sterilizer or used to sterilize and treat waste water.

- The contractor has incorporated the electrochemical cell into a sterilizer. Tests are being conducted to establish ozone exposures required to reliably sterilize surgical goods.

g. The **Expert System for Trauma Management** is a technology watch for new developments in artificial intelligence and expert systems (AI/ES) which can be applied to military medicine.

- A database of AI/ES activities was developed, and an advisory panel of experts is being identified and will be assembled to evaluate commercial and academic systems under development for potential applications to military medicine.

h. The **Far Forward Suction Apparatus** is a compact, line or battery-operated suction pump and collection vessel that allows the user to select vacuum level in either an intermittent or continuous suction mode. This unit will support requirements for oropharyngeal, nasogastric, and peritoneal suction.

- A market investigation was completed and only one nondevelopmental item was identified that meets the CBTDEV's requirements. An experimental prototype was demonstrated to the CBTDEV, which was well received. As a result, final development and FDA licensing of the new unit are being closely monitored. The design of the device is now complete, and it is currently undergoing environmental tests. A submittal to the FDA is anticipated in CY95. Once FDA licensing is complete, product information, including essential characteristics, will be forwarded to the U.S. Army Medical Materiel Agency (USAMMA) for type classification and procurement.

i. The **Field OB/GYN Examination Table** is a lightweight portable patient treatment platform for OB/GYN examination in field medical facilities. Initial efforts focused on modifying an existing patient examination platform, such as the Field Examination Chair or the Far Forward Surgical Table.

- Based on the recommendations of the Defense Medical Standardization Board (DMSB) Joint Services Nursing Group (JSNG), a field optometry chair was modified with examination stirrups. The prototype chair was examined by the JSNG and the Clinical Review Group and found to be suitable. The TDP has been prepared.

j. The **M43A1 Protective Mask Vision Correction (PM ALSE-Prime MATDEV)** is a spectacle lens frame designed to hold the aviator's prescription lenses. The frontsert attaches to the interpupillary distance staple of the M43A1 mask. The frontsert will be fabricated from materials that will withstand chemical agent attack and be decontaminable.

- System development and testing have been completed, and the vision corrective frontsert has been approved for use by the aviation community. In preparation for transition to the AMEDD, an update of the TDP was initiated. A low rate initial production of 8,000 frontserts began in CY94.

k. The **Multipurpose Centrifuge (TR/BL)** is a compact, line or battery-operated instrument with a unique rotor to accommodate hematocrit tubes and centrifuge tubes of different sizes. Using a microprocessor-controlled motor, different patient samples can be easily prepared for laboratory analysis under field conditions.

- Phase II of the SBIR contract was completed in CY94, and prototypes were delivered to USAMMDA in accordance with the contract. The contractor, Technical Research Associates, Inc., is expected to use non-federal capital to pursue private sector applications of this research.

l. A **Portable Rugged Laser Optometer (RP/BL)** is the objective of an SBIR contract to build a compact device capable of measuring the refractive error in the vision of a soldier in an austere field environment. Unlike current devices which use lenses and must be operated by a trained practitioner, the laser optometer will be automated and require seconds for an accurate measurement.

- Phase II of the SBIR was successfully completed in CY94. The contractor is establishing a Phase III partnership for commercialization.

m. The **Vision Corrective Eyewear (VCE)** program includes co-management of, or development consultation on, non-AMEDD product developments. Vision correction or vision correction compatibility are requirements for a range of products. The major categories include laser and ballistic protective eyewear, protective masks, and aviator helmet systems. The VCE, developed by non-AMEDD communities, transitions to the AMEDD at fielding. The eyewear design can affect optometry personnel requirements, training requirements, and TOE optometry and optical fabrication equipment sets. In CY94:

- PM soldier/Natick Research, Development and Engineering Center's Type Classification Review Panel recommended adopting the Ballistic-Laser Protective Spectacles (B-LPS) for use by the spectacle-wearing soldier. The B-LPS uses the AMEDD-developed Prescription Lens Carrier (PLC). The USAMMDA modified the PLC to eliminate a safety hazard.

- Vision correction support was provided for the Advanced Technology Demonstration of Respiratory Protection 21st Century. The lens carrier design includes features from the B-LPS PLC.

- Special Protective Eyewear Cylindrical System (SPECS) is the Natick-developed protective eyewear being recommended for non-spectacle wearing soldiers. The USAMMDA evaluated the design to determine impact of developing a prescription lens version.

- A recommendation for Army evaluation of the Air Force candidate for the new aviator frame was provided to the Human Systems Division, Brooks Air Force Base.

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QUALITY ASSURANCE OFFICE

During 1994, the Quality Assurance Office was kept very busy monitoring ongoing studies, reviewing new protocols, and regulatory submissions, awarding new contracts and conducting internal audits. Most of these projects were accomplished by two individuals, due to a temporary decrease in manpower.

Despite the decreased manpower, the Quality Assurance Office was able to maintain a monitoring schedule which included monitoring studies at USAMRIID; WRAIR; the Center for Vaccine Development, a Phase I/II Biological Systems contractor; and the South Florida Drug Research Corporation, a Phase I Pharmaceutical Systems contractor. Additionally, overseas monitoring visits were conducted in England - a Good Manufacturing Practices (GMP) inspection of a Botulinum Toxoid manufacturing contractor and an audit of previously conducted Pyridostigmine Bromide studies that were submitted in the New Drug Application (NDA); Israel - shigella studies; Peru - cholera studies; Thailand - malaria studies; and Canada - current HI-6 studies.

Quality Assurance Office personnel reviewed the Pyridostigmine Bromide NDA, submitted in 1QCY94, the Tularemia Product License Application (PLA), to be submitted in 3QCY95, and audited safety and immunogenicity data in preparation of the Argentine Hemorrhagic Fever Vaccine PLA.

A Request for Proposal (RFP) was prepared to replace the current Regulatory Affairs contract scheduled to expire 3QCY94. The contract was extended because of continuing negotiations with proposers, however, contract award is imminent. During the same timeframe, the incumbent archiving contract was replaced through competitive award of a new contract.

Miscellaneous items completed by the QA Office include completion of the Human Use Studies Program (HUSP), due to no small effort by the members of the Working Group, representing each CONUS laboratory. The draft regulation was submitted to HQ, USAMRMC in early March 1994. For the first time in corporate memory, the FDA audited a clinical study conducted by USAMRIID; through co-operation by the Product Manager, the QA Office, the Principal Investigator and his staff, the data contained in the pivotal study allowed the licensure of the Plague Vaccine. Finally, an internal audit of USAMMDA IND sponsored files was conducted at the request of the Commander; findings were presented to him at the end of December 1994.

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RESOURCES MANAGEMENT

1. **Project Management Division Database (PMDD) and Product Management Database System (PMDS)**: The development of two database systems that will assist the Project and Product Managers in planning and programming product development costs neared completion. The PMDD system will enable the Project Managers to designate the Product Manager-product pairing and to allocate total DA Project allotments to specific products. The PMDS system will enable the Product Managers to identify planned activities through integrated commercial project management software with funding requirements associated with each of their products and to generate Business Plans. Information on planned, committed, and obligated funds will be displayed on the PMDD and PMDS reports. In addition, the planned activities from PMDS become the baseline data for the Financial Management System (FMS) and the General Analysis/Priority System (GAPS) through a transfer procedure. FMS has also undergone further enhancements to improve the system's responsiveness and performance, including making FMS a multiuser system. Automated linking of the four systems will provide tremendous productivity gains for USAMMDA as Project Managers can react faster to changes in project plans and execution requirements and share the updated plan with development partners in the laboratories and contract sites.

2. **Project Management Documentation Support Contract**: The PMSD continued as the Contracting Officer's Representative (COR) for the support contract to provide the Project Managers with timely, high quality program and project management documentation, cost estimates and analytical services. For the second consecutive year, the level of effort declined as the amount of original documentation to support new transitions and sustain on-going product development declined. The contract staff's familiarity with documentation requirements for current development products also reduced the effort needed to produce finished documents. The number of cost estimating actions stayed at the same high level as the previous year due to an increased number of milestone reviews and support for contract efforts. The quality and timeliness of the contract-produced estimates remained at the same high level achieved in the previous year. The contractor provided significant support in data collection and reduction necessary to provide participants with adequate program knowledge and status to complete the AMEDD annual medical Mission Area Materiel Plan. Increased USAMMDA staff awareness of the cost and value of contractor support in preparing each deliverable resulted in an increase in workload in support of the Applied Medical Systems Project Management Division. Change of personnel in the contractor's computer programming staff caused significant turbulence in the automated financial management and program analysis software support. The contractor was provided with direction to improve support or face reductions in fee and future business.

3. **Medical Research, Development, and Acquisition (RDA) Mission Area Materiel Plan (MAMP):** Beginning in CY94, the AMEDD Center and School (AMEDDC&S) took the lead in organizing and executing the AMEDD's MAMP. The 1994 Medical RDA MAMP Meeting (1-2 August 1994) performed product assessments for evaluating the U.S. Army Medical Research, Development, Acquisition and Logistics Command (USAMRDALC) (now known as USAMRMC) Research and Development (R&D) program with respect to medical-related combat requirements. Representatives from USAMMDA, AMEDDC&S, and USAMMA, evaluated and formally assessed 56 products against 13 operational capability requirements (OCRs). The OCRs, based on AMEDD deficiencies, enhancements, and obsolescences, are weighed in terms of relative importance. A paired comparison technique was used to determine the relative weight of AMEDD OCRs used in the ranking process. A medical materiel "fix" was integrated to pinpoint the highest payoff for advanced development efforts. Prevention was valued relatively more important than either treatment or evacuation. The value-added concept, which measures regional applicability and level of care/intervention, determined the relative value to a field commander of keeping troops on line by factoring in preventive efforts, return to duty actions, or treatment in fixed facilities, against the probability of a product's use in one of the six Unified Command geographical regions. The evaluation process was further enhanced with the addition of morbidity and mortality concepts. A logistical confidence component was added to the scoring process to assess the logistical supportability (provisioning, shelf-life, size, transportability, environmental requirements, durability, maintainability, and power requirements).

Results of the MAMP meeting, signed by command representatives of the AMEDDC&S and the USAMRDALC (now known as USAMRMC), were distributed to all interested parties. The MAMP results are used as a tool to determine program planning and execution.

INFORMATION MANAGEMENT

Automated Data Processing Support: Installation was completed on the LAN manager-based Pathworks network which provides increased capabilities for the users. Management of the network is more efficient due to Windows-based network software, increased security features and centralized printer controls. CC:Mail was installed on the network providing users with an easier interface to the world-wide electronic mail system. Bulletin boards and in-house mailing lists have decreased the need for hardcopy distribution and have put more tools on the user's desktop by electronic means. The increasing use of network-based applications has provided for a centralized database system for the Product Managers, Project Managers and PMSD staff. A network was established in the Visual Information Section to allow for connectivity of all graphics stations and printers. The illustrators created a new layout for the conference room as well as a new backdrop for the televideo room. A brochure was produced which describes the services that are provided by the Visual Information Section.

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HUMAN RESOURCES

Planning was initiated during the year to effect military reductions based on the TAA-01 Study and civilian reductions imposed by HQDA Affordability Analysis. The divisions implemented plans to reduce manpower over the next five years by assessing mission requirements and redistribution of workload. Military authorizations were reduced by 10 (a 50% reduction) and civilian authorizations by 11 (a reduction of 21%).

There were no civilian accessions, one employee was promoted, and one individual resigned to accept employment in the private sector.

Military personnel actions included one promotion, two accessions, one retirement, and one transter.

Civilian Awards:
- 25 exceptional performance evaluations
- 29 performance awards
- 1 Commander's Award for Civilian Service
- 5 Time-Off Awards
- 2 Invention Awards
- 13 On-the-Spot Awards

Military Awards:
- 1 Meritorious Service Medal
- 1 Legion of Merit
- 1 "A" Prefix Designator

A list of USAMMDA's key personnel and unit strength is presented in Appendix F.

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FISCAL PERFORMANCE

1. **In-House**: In FY94, USAMMDA's In-House fiscal execution exceeded the USAMRMC disbursement target by 73 percent. Obligations were less than one percent below the established target.

	Allotment	Obligations	Disbursements
FY 1994 Dollars ($000)	4,801	4,765	4,243
Target (%)		100	.51
Actual (%)		99	88

2. **Program Wide**: Disbursements exceeded the target established for the FY94 total program. Extramural and total program disbursement targets were exceeded in Program Element 644807 (6.4), and the laboratory disbursement target was exceeded in Program Element 643807 (6.3b). Performance in the command-wide development program fell below levels reached in FY93 in both obligation and disbursement execution percentage, attributable to a drop in extramural activity. Laboratory, extramural and total program obligations were within 1% of target. Fiscal execution performance at the project level is provided in Appendix G.

	Allotment	Obligations	Disbursements
FY 1994 Dollars ($000)	30,341	29,942	16,034
Target (%)		100	51
Actual (%)		99	53

The advanced development program identified over $3M for redistribution to high priority USAMRMC requirements during FY94. The early identification of unexecutable funds can be attributed to a strict review of funding requirements as outlined in the Business Plans. This enabled Project Managers to anticipate at an earlier period funds which are excess to previously anticipated requirements.

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LOGISTICS MANAGEMENT

1. **Integrated Logistics Support and MANPRINT Documentation**: The following Integrated Logistic Support Plans (ILSP) were prepared in support of Milestone IPRs for USAMMDA products.

MONTH	TYPE	PRODUCT
January	MS IIIa	Tularemia Live Vaccine
March	MS I	Botulism Immune Globulin (F(ab')2), Heptavalent, Equine
March	MS I	Rift Valley Fever Vaccine
March	MS I	Antimalarial Drug, Azithromycin
May	MS IIIa	Argentine Hemorrhagic Fever Vaccine
June	MS II	Enterotoxigenic Escherichia Coli, Whole Cell Plus B Subunit Vaccine
June	MS I	Antimalarial Drug, Halofantrine Prophylactic
November	MS II	Q Fever CMR Extract Vaccine
December	MS I	Cyanide Pretreatment

2. **Other Product Specfic Documents**:

Division	Product	Document
AMSPMD	Field Medical Oxygen Generating and Distribution System	Safety Assessment Report Logistic Demo Plan Logistic Demo Report System MANPRINT Management Plan ILSP Hazard Analysis Operators Manual Maintenance Manual Repair Parts and Special Tools List Training Plan
	Liquid Oxygen System	Basis of Issue Plan/ Qualitative & Quantitative Personnel Requirements Information

Division	Product	Document
	Portable Field X-Ray Table	Transition Plan
BSPMD	Campylobacter Vaccine	ILSP
	Ricin Vaccine	ILSP
PSPMD	Antimicrobial Dermal Dressing	ILSP
	Nerve Agent Antidote System HI-6	ILSP

3. **General Logistics, Test and Documentation Support**:

- Site support for user test of Antimicrobial Dermal Dressing.

- Implemented the Memorandum of Agreement between USAMMDA and NASA for Oxygen Systems Hazard Analysis.

- Reviewed DA PAM 700-XXX, Army Acquisition Procedures.

- Coordinated multi-agency meeting to update AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel.

- Prepared Logistic Assessments for all USAMMDA products for the 1994 MAMP Conference.

- Reviewed DA PAM 73-3, Critical Operational Issues and Criteria.

- Revised the Program Manager's Toolbox to encompass unique Medical Materiel Requirements.

- Coordinated the review and analysis of all incoming Requirements Documents.

PRESENTATIONS

Abbasi, Intisar A., Pre-transition Requirements for Military Medical Product Development and Role of U.S. Army Medical Materiel Development Activity (USAMMDA), Combat Casualty Care Research Program, Review and Analysis, Rockville, Maryland, March 1994

Caldwell, Donald W. and Nelson, James H., "Essential Characteristics of the Field Anesthesia Machine," presented to the Tri-Service Anesthesiology Consultants, Fort Sam Houston, TX, August 1994

Clawson, Ronald E., Briefing on Interactions with Industry for the Industrial College of the Armed Forces, Ft. Detrick, MD, February 1994

Clawson, Ronald E., Presentation on the Nerve Agent Antidote System to the Shoresh Conference, Tel Aviv, Israel, December 1994

Lightner, Lawrence K., LTC, Briefing on the Medical Research and Development Process at the 1994 USAREUR and 7th Army AMEDD Training Symposium, Garmisch, Germany, April 1994.

Nelson, James H., "Advances in Field Medical Equipment Technology," presented at the Second Annual Field Medicine Conference, Fort Bragg, NC, April-May 1994

Paschal, Charles R., "Improved Armored Ambulance," presented at the 1994 Army Medical Evacuation Conference, San Antonio, TX, March 1994

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MAJOR TRAINING EVENTS ATTENDED

Abbasi, Intisar A., MAJ, Fundamentals of Systems Acquisition Management Course, Fort Belvoir, VA, January 1994

Abbasi, Intisar A., MAJ, Intermediate Systems Acquisition Management Course, Fort Belvoir, VA, July 1994

Abbasi, Intisar, A., Drug Stability, Washington, DC, April 1994

Albright, Deanna W., Drug & Alcohol Awareness Training for Managers & Supervisors, Fort Detrick, MD, March 1994

Albright, Deanna W., Prevention of Sexual Harassment (POSH) for Supervisors, Fort Detrick, MD, March 1994

Albright, Deanna W., Sponsorship Training, Fort Detrick, MD, April 1994

Albright, Deanna W., MARKS Refresher, Fort Detrick, MD, May 1994

Alleman, Susan I., Business Software and Tools, Wilson College, Chambersburg, PA, December 1994

Arnold, Mark F., Intermediate Systems Acquisition Course, Fort Belvoir, VA, March 1994

Arnold, Mark F., Best-Value Source Selection, Fort Detrick, MD, April 1994

Arnold, Mark F., Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Arnold, Mark F., Intermediate Systems Acquisition, Fort Belvoir, April 1994

Balady, Michael A., Quality Assurance & Control for Biotechnology, E. Brunswick, NJ, February 1994

Balady, Michael A., Preparing Clinical Protocols and Managing Clinical Investigations, E. Brunswick, NJ, March 94

Balady, Michael A., Practical Considerations in Preparing Investigational New Drug and New Drug Applications, E. Brunswick, NJ, March 1994

Berte, Stephen B., Design and Validation of Biotechnology Facilities, E. Brunswick, NJ, March 1994

Berte, Stephen B., Practical Considerations in Preparing Investigational New Drug and New Drug Applications, E. Brunswick, NJ, March 1994

Berte, Stephen B., Good Clinical Practices, University of Wisconsin, Frederick, MD, June 1994

Berte, Stephen B., Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Boedecker, David L., Best-Value Source Selection, Fort Detrick, MD, April 1994

Boswell, Lydia L., MARKS Refresher, Fort Detrick, MD, May 1994

Boswell, Lydia L., Striving for Excellence - Management Skills for the Office Professional, Fort Detrick, MD, June 1994

Bowers, Elizabeth A., Powerpoint 3.0, Fort Detrick, MD, February 1994

Bowers, Elizabeth A., WordPerfect for Windows 6.0, Fort Detrick, MD, April 1994

Bowers, Elizabeth A., Intro to Harvard Graphics 3.05, Fort Detrick, MD, July 1994

Braitman, David J., Post Graduate Course in Clinical Pharmacology, Drug Development and Regulation, Boston, MA, February 1994

Braitman, David J., LTC, Introduction to the Regulatory Process Course, Madison, WI, May 1994

Braitman, David J., Lotus 1-2-3, Fort Detrick, MD, May 1994

Braitman, David J., Practical Considerations in Preparing Investigational NDAs, Chicago, IL, June 1994

Braitman, David J., Preparing Clinical Protocols and Managing Clinical Investigations, Chicago, IL, June 1994

Braitman, David J., Design, Managing and Monitoring Clinical Trials, Philadelphia, PA, September 1994

Braitman, David J., Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Braitman, David J., Project Scheduling in Pharmaceutical Development - Resources, Baltimore, MD, October 1994

Braitman, David J., Good Clinical Practices, East Brunswick, NJ, November 1994

Braitman, David J., Fundamentals of Systems Acquisition Management, Los Angeles, CA, July 1994

Brown, Mark W., Differential Equations, Frederick Community College, Frederick, MD, January-May 1994

Brown, Mark W., Introductory Physics I, Frederick Community College, Frederick, MD, December 1994

Brown, Mark W., Introduction to Computers and Information Processing, Frederick Community College, Frederick, MD, December 1994

Burman, Mary C., Monitoring Clinical Drug Studies: Intermediate, Aston, PA, February 1994

Burman, Mary C., Auditing Techniques for QA & Clinical Research Professionals, Aston, PA, March 1994

Burman, Mary C., Reviewer and Inspection, Bethesda, MD, March 1994

Burman, Mary C., Sponsorship Training, Fort Detrick, MD, April 1994

Burman, Mary C., Best-Value Source Selection, Fort Detrick, MD, April 1994

Burman, Mary C., Quality Assurance Fundamentals, Rock Island, IL, August 1994

Caldwell, Donald W., Best-Value Source Selection, Fort Detrick, MD, April 1994

Caldwell, Donald W., Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Caldwell, Donald W., Lotus 1-2-3 Version 4, Fort Detrick, MD, May 1994

Clawson, Ronald E., FDA Accelerated Approval, Boston, MA, September 1994

Cole, Janice M., WordPerfect for Windows 6.0, Fort Detrick, MD, April 1994

Cole, Janice M., Introduction to Windows 3.1, Fort Detrick, MD, April 1994

Cole, Janice M., Lotus 1-2-3 Version 4, Fort Detrick, MD, May 1994

Cole, Janice M., Resource Management Budget-Correspondence, Fort Benjamin-Harrison, IN, October 1994

Cole, Janice M., DTIC 94 Annual Users Meeting and Conference, Crystal City, VA, November 1994

Cutsail, Cindy E., WordPerfect for Windows 6.0, Fort Detrick, MD, August 1994

Cutsail, Cindy E., MARKS Refresher Course, Fort Detrick, MD, September 1994

Danley, David L., Program Management Course, Fort Belvoir, VA, January-June 1994

Doughty, D. Scott, Best-Value Source Selection, Fort Detrick, MD, April 1994

Doughty, D. Scott, Instrumentation for Engineering Measurements, East Brunswick, NJ, August 1994

Doughty, D. Scott, Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Ferguson, Warren R., Civilian Personnel Managers Workshop-Acquisition Workforce, Herndon, VA, March 1994

Gere, Jeffrey A., LTC, Program Management, Springfield, VA, May 1994

Gere, Jeffrey A., LTC, Lotus 1-2-3 Version 4.0, Ft Detrick, MD, May 1994

Gere, Jeffrey A., LTC, Designing, Managing and Monitoring Clinical Trials, Philadelphia, PA, September 1994

Gere, Jeffrey A., LTC, Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Gilbreath, Micheal J., Microbiological Control and Validation, E. Brunswick, NJ, March 1994

Gilbreath, Micheal J., Fundamentals of System Acqusition Management, Fort Belvoir, VA, March 1994

Gilbreath, Micheal J., Intermediate Systems Acquisition, Fort Belvoir, April 1994

Gilbreath, Micheal J., Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Gula, Philip R., Best-Value Source Selection, Fort Detrick, MD, April 1994

Gula, Philip R., Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Hathaway, Mary A., WordPerfect for Windows 6.0, Fort Detrick, MD, April 1994

Hathaway, Mary A., Introduction to Windows 3.1, Fort Detrick, MD, June 1994

Hathaway, Mary A., MARKS Refresher, Fort Detrick, MD, September 1994

Hathaway, Cecil C., Intermediate Acquisition Logistics, St. Louis, MO, March 1994

Hathaway, Cecil C., Logistics Support Analysis, Fort Lee, VA, May 1994

Hathaway, Cecil C., Reliability and Maintainability, Dayton, OH, July 1994

Higgins, Yvonne K., Quality Assurance & Control for Biotechnology, E. Brunswick, NJ, February 1994

Higgins, Yvonne K., Practical Considerations in Preparing Investigational New Drug and New Drug Applications, E. Brunswick, NJ, March 1994

Kenyon, Richard H., Cost Management for Clinical Trials, Washington, DC, February 1994

Langford, Michael J., Regulatory Affairs Professional Meeting, Washington, DC, October 1994

Langford, Michael J., Accelerated Project Scheduler 6, Fort Detrick, Frederick, MD, November 1994

Lee, Terry J., Intermediate Systems Acquisition Course, Fort Belvoir, VA, May 1994

Lewis, George E., Management for Research and Development, Massachusetts Institute of Technology, Cambridge, MA, June 1994

Liu, Dai-Kee, Intermediate Systems Acquisition, Fort Belvoir, VA, March 1994

Liu, Dai-Kee, Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Martin, Louie D., Analytic Geometry, Hagerstown Community College, Hagerstown, MD, May 1994

Martin, Louie D., DOS 6.0 Introduction, Fort Detrick, MD, July 1994

Martin, Louie D., Calculus 1, Hagerstown Junior College, Hagerstown, MD, December 1994

McDonnell, Elisabeth A., Drug & Alcohol Awareness Training for Managers & Supervisors, Fort Detrick, MD, March 1994

McDonnell, Elisabeth A., Prevention of Sexual Harassment (POSH) for Supervisors, Fort Detrick, MD, March 1994

McDonnell, Elisabeth A., Leadership, Education and Development (LEAD) Course, Frederick, MD, April 1994

Morgan, Sharon L., Lotus 1-2-3 Version 4, Fort Detrick, MD, May 1994

Morgan, Sharon L., MARKS Refresher, Fort Detrick, MD, September 1994

Nelson, James H., Approaches to the Clinical Evaluation of Medical Devices, Rockville, MD, December 1994

Pace, Judith G., Good Clinical Practices, University of Wisconsin, Frederick, MD, June 1994

Pace, Judith G., Accelerated Project Scheduler 6, Fort Detrick, Frederick, MD, October 1994

Pace, Judith G., Adjuvants: Food and Drug Administration, Fort Detrick, Frederick, MD, November 1994

Paschal, Charles R., Best-Value Source Selection, Fort Detrick, MD, April 1994

Paschal, Charles R., Pediatric Advanced Life Support, Frederick Memorial Hospital, Frederick, MD, October 1994

Painter, Gail L., DOS 5-Intro, Fort Detrick, MD, March 1994

Poole, Anna M., Intermediate Contractor Performance Measurement, St. Louis, MO, April 1994

Poole, Anna M., Supervisory Development Correspondence Course, Phase I, Fort Detrick, MD, July 1994

Priebe, Rebecca A., Network and Operations Management Symposium, Kissimmee, FL, February 1994

Priebe, Rebecca A., Windows 3.1, Fort Detrick, MD April 1994

Priebe, Rebecca A., VMS Operations, Landover, MD April 1994

Priebe, Rebecca A., Troubleshooting Local Area Networks, Landover, MD, June 1994

Priebe, Rebecca A., Advanced DOS 6.0, Frederick, MD, August 1994

Priebe, Rebecca A., Accelerated Project Scheduler 6, Fort Detrick, Frederick, MD, October 1994

Priebe, Rebecca A., Pathworks V5: Install and Configuring the Open VMS Server, Landover, MD, November 1994

Reams, William H., Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Salisbury, Lloyd L., Financial Management and Engineering, University of Michigan, Ann Arbor, MI, May 1994

Salisbury, Lloyd L., Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Salisbury, Lloyd L., Design for Environment; Fundamentals for Sustainable Development, Ann Arbor, MI, June 1994

Sampson, James R., AT&T Video Facilitator Training Forum, Greensboro, NC, June 1994

Sampson, James R., Reliability and Maintainability, Dayton, OH, July 1994

Sampson, James R., Intermediate Acquisition Logistics, St. Louis, MO, July 1994

Schieferstein, George J., Drug Safety Evaluation Course, Philadelphia, PA, January 1994

Schieferstein, George J., Intermediate Systems Acquisition, Defense Systems Management College, Hanscomb AFB, MA, May 1994

Schieferstein, George, J., Good Clinical Practices, University of Wisconsin, Frederick, MD, June 1994

Schieferstein, George, J., WordPerfect for Windows 6.0, Fort Detrick, MD, August 1994

Schieferstein, George, J., Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Sheffer, Linda J., Lotus 1-2-3 Version 4, Fort Detrick, MD, May 1994

Sheffer, Linda J., Intermediate Contractor Performance Measurement Fundamentals, Fort Belvoir, VA, August 1994

Stewart, James R., Postgraduate Course Clinical Pharmacology, Drug Development and Regulation, Boston, MA, February 1994

Stewart, James R., Intermediate Systems Acquisition, Fort Belvoir, VA, September 1994

Stitely, Carol A., WordPerfect for Windows 6.0, Fort Detrick, MD, April 1994

Stitely, Gene W., Photoshop Conference, NY, NY, July 1994

Walsh, David J., Accelerated Project Scheduler 6, Fort Detrick, MD, October 1994

Walton, Lori A., Supervisor Development Correspondence Course, Fort Detrick, MD, January 1994

Walton, Lori A., Good Manufacturing Practices for Bioprocesses, UMBC, Baltimore, MD, May 1994

Walton, Lori A., Focus on Protecting Human Subjects in the Federal Government, Bethesda, MD, June 1994

Walton, Lori A., Best-Value Source Selection, Fort Detrick, MD, April 1994

Walton, Lori A., Quality Control and Quality Assurance of Biotechnology Products, Baltimore, MD, December 1994

Wivell, Stephanie V., Military Standards Requisitioning and Issue Procedures (MILSTRIP), Fort Detrick, MD August 1994

Zittle, Virginia L., MARKS Refresher Course, Fort Detrick, MD, August 1994

DISTINGUISHED VISITORS

Dr. Tim Rubidge, Chemical and Biological Defence Establishment, Porton Down, United Kingdom. Development of HI-6, 1 February 1994.

Dr. Richard John Horton, Dr. Bryan Deane, Dr. Cletus Ugwuegbulam, Ms. Hilary Christodoulou, SmithKline Beecham Pharmaceuticals, Hertfordshire, United Kingdom. Antimalarial Drug WR238605/Antileishmanial Drug WR6026 CRDA, 8 September 1994.

Dr. Luc Ravinet, Dr. Jacquie Berthe, Dr. J.R. Dormoy, Mme. Christiane Blanchemanche, Elf Sanofi Pharma, s.a., Paris, France. Antimalarial Drug WR238605/Antileishmanial Drug WR6026 CRDA, 8 September 1994.

Dr. Manfred Green, Israeli Defense Force. Discussion on Phase 2b Shigella vaccine study and proposed ETEC clinical trials in Israeli soldiers, 9 March 1994.

Drs. Peter Hambleton, Howard Trantor, Christopher Wiblin, Barry Thornton, Clifford Shone, and Stephen Prior, Centre for Applied Microbiology and Research, Porton Down, United Kingdom. Quarterly Botulism Toxoid Vaccine progress meeting, 28 April 1994.

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DISTRIBUTION LIST

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-ZB
Fort Detrick
Frederick, MD 21702-5012

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RMI-S
Fort Detrick
Frederick, MD 21702-5012

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLA
Fort Detrick
Frederick, MD 21702-5012

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLB
Fort Detrick
Frederick, MD 21702-5012

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLC
Fort Detrick
Frederick, MD 21702-5012

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLD
Fort Detrick
Frederick, MD 21702-5012

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLE
Fort Detrick
Frederick, MD 21702-5012

Commander
U.S. Army Medical Research Institute of Infectious Diseases, Bldg. 1425
Fort Detrick
Frederick, MD 21702-5011

Commander
U.S. Army Medical Research Institute of Chemical Defense
Bldg. E3100, Edgewood Area
Aberdeen Proving Ground, MD 21010-5425

Commander
U.S. Army Aeromedical Research Laboratory
Bldg. 8708
Fort Rucker, AL 36362-5292

Commander
U.S. Army Institute of Surgical Research
Bldg. 2653
Fort Sam Houston, TX 78234-6200

Director
U.S. Army Medical Research Acquisition Activity
Bldg. 820
Fort Detrick
Frederick, MD 21702-5014

Commander
U.S. Army Biomedical Research and Development Laboratory
Bldg. 568
Fort Detrick
Frederick, MD 21702-5010

Commander
U.S. Army Research Institute of Environmental Medicine
Bldg. 42
Natick, MA 01760-5007

Director
Walter Reed Army Institute of Research
Bldg. 40
Washington, DC 20307-5100

HQDA (DASG-LO)
5109 Leesburg Pike
Falls Church, VA 22041-3258

HQDA (DASG-HCO)
5109 Leesburg Pike
Falls Church, VA 22041-3258

Commander
U.S. Army Medical Department Center and School
ATTN: MCCS-FMC
Fort Sam Houston, TX 78234-6100

Commander
U.S. Army Medical Department Center and School
ATTN: MCCS-FB
Fort Sam Houston, TX 78234-6100

Commander
U.S. Army Medical Materiel Agency
ATTN: MCMR-MMZ-RM
Fort Detrick
Frederick, MD 21702-5001

Commander
U.S. Army Training and Doctrine Command
ATTN: ATCD
Fort Monroe, VA 23651

Commander
U.S. Army Forces Command
ATTN: AFLG-FME
Fort McPherson, GA 30330-6000

Commander
1st Special Operations Command
ATTN: AFVS-CG
Fort Bragg, NC 28307

Chief of Staff
U.S. Central Command
MacDill AFB, FL 33608

Chief of Staff
8th United States Army
U.S. Forces Korea
APO San Francisco, 96301-0009

Commander
U.S. Army Laboratory Command
ATTN: AMDEL-CD
Adelphi, MD 20783-1145

Commander
10th Mountain Division
ATTN: Division Surgeon
Fort Drum, NY 13602-5000

Commanding General
Marine Corps Research, Development, and Acquisition Command
ATTN: Code SSC/GP
Washington, DC 20380-0001

Commander
U.S. Army Human Engineering Laboratory
Aberdeen Proving Ground, MD 21005

Commander
U.S. Army Aviation and Troop Command
ATTN: AMSAT-I-FIS
St. Louis, MO 63120-1787

Commander
U.S. Army Materiel Command
ATTN: AMCDE
5001 Eisenhower Avenue
Alexandria, VA 22333

Commander
U.S. Army Natick Research and
Development Command
ATTN: STRNC-Z
Natick, MA 01760

Commander
U.S. Army Research Office
P.O. Box 12211
Research Triangle Park, NC 27709-2211

Staff Director
Defense Medical Standardization Board
Fort Detrick
Frederick, MD 21702-5013

Commander
6th Infantry Division (Light)
Fort Richardson, AK 99505

Commander
U.S. Army John F. Kennedy Special
Warfare Center
ATTN: ATSU-CG
Fort Bragg, NC 28307

Commander
9th Infantry Division
ATTN: AFVO-CG
Fort Lewis, WA 98433-5000

Commander
44th Medical Brigade
Fort Bragg, NC 28307-5000

Commander
18th Medical Command
ATTN: EAMC-CD
APO San Francisco, CA 96301-0080

Commander
7th Medical Command
APO New York 09102

Commanding Officer
Naval Medical Research and
Development Command
National Naval Medical Center
Bethesda, MD 20014

HQ USAF/SGPT
Bolling Air Force Base
Washington, DC 20332-6188

HQ USAF/SGHR
Bolling Air Force Base
Washington, DC 20332-6188

Commander
Center for Health Promotion & Preventive
Medicine
Aberdeen Proving Ground, MD
21010-5422

Defense Technical Information Center
ATTN: DTIC-DDA
Alexandria, VA 22314-6145

HQ EUCOM
Office of the Command Surgeon
ATTN: Chief Operations/Logistics
Division
APO New York 09128

HQ AFSC/XTH
Andrews AFB, MD 20334-5000

HQ HSD/CC-XA
Brooks AFB, TX 78235-5000

Department of the Navy
Naval Sea Systems Command
ATTN: Code 55X25/Mr. Pete Jung
Washington, DC 20362-5101

Commander
U.S. Army Materiel Systems Analysis
Activity
ATTN: AMXSY-L
Aberdeen Proving Ground, MD 21010

APPENDIX A

COMMONLY USED ACRONYMS

AMEDD	Army Medical Department
AMSPMD	Applied Medical Systems Project Management Division
BRAC	Base Realignment and Closure Act
BSPMD	Biological Systems Project Management Division
CAMR	Center for Applied Microbiology
cGCP	Current Good Clinical Practices
cGMP	Current Good Manufacturing Practices
COR	Contracting Officer's Representative
COEA	Cost and Operational Effectiveness Analysis
CRDA	Collaborative Research and Development Agreement
CY	Calendar Year
DOD	Department of Defense
DPSC	Defense Personnel Support Center
E-CBRS	Enhanced Concept Base Requirement System
FY	Fiscal Year
FDA	Food and Drug Administration
FMOGDS	Field Medical Oxygen Generation and Distribution System
GAPS	General Analysis/Priority System
IND	Investigational New Drug Application
IPR	In-Process Review
IRCP	Integrated Regulatory Compliance Program
JWG	Joint Working Group
MC	Materiel Change
MAMP	Mission Area Materiel Plan
MNS	Mission Needs Statement
NDA	New Drug Application
NDI	Non-development Item
ORD	Operational Requirements Document
PLA	Product License Application
PMSD	Project Management Support Division
PPBES	Planning, Programming, Budgeting and Execution System
PSPMD	Pharmaceutical Systems Project Management Division
RFP	Request for Proposals
SBIR	Small Business Innovation Research
TDP	Technical Data Package
TEMP	Test and Evaluation Master Plan
TWG	Technical Working Group
TWIG	Test Integration Working Group
RDA	Research, Development and Acquisition
USAARL	U.S. Army Aeromedical Research Laboratory

USABRDL	U.S. Army Biomedical Research and Development Laboratory
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDALC	U.S. Army Medical Research, Development, Acquisition and Logistics Command
USAMRDC	U.S. Army Medical Research and Development Command
USAMRMC	U.S. Army Medical Research and Materiel Command
USAMRIID	U.S. Army Research Institute of Infectious Diseases
USARIEM	U.S. Army Research Institute of Environmental Medicine
WRAIR	Walter Reed Army Institute of Research

PAID (PRODUCT ASSOCIATION IDENTIFICATION) CODES

A system to identify significantly contributing Labs/ Contractors/CRDA Partners, etc., with products.

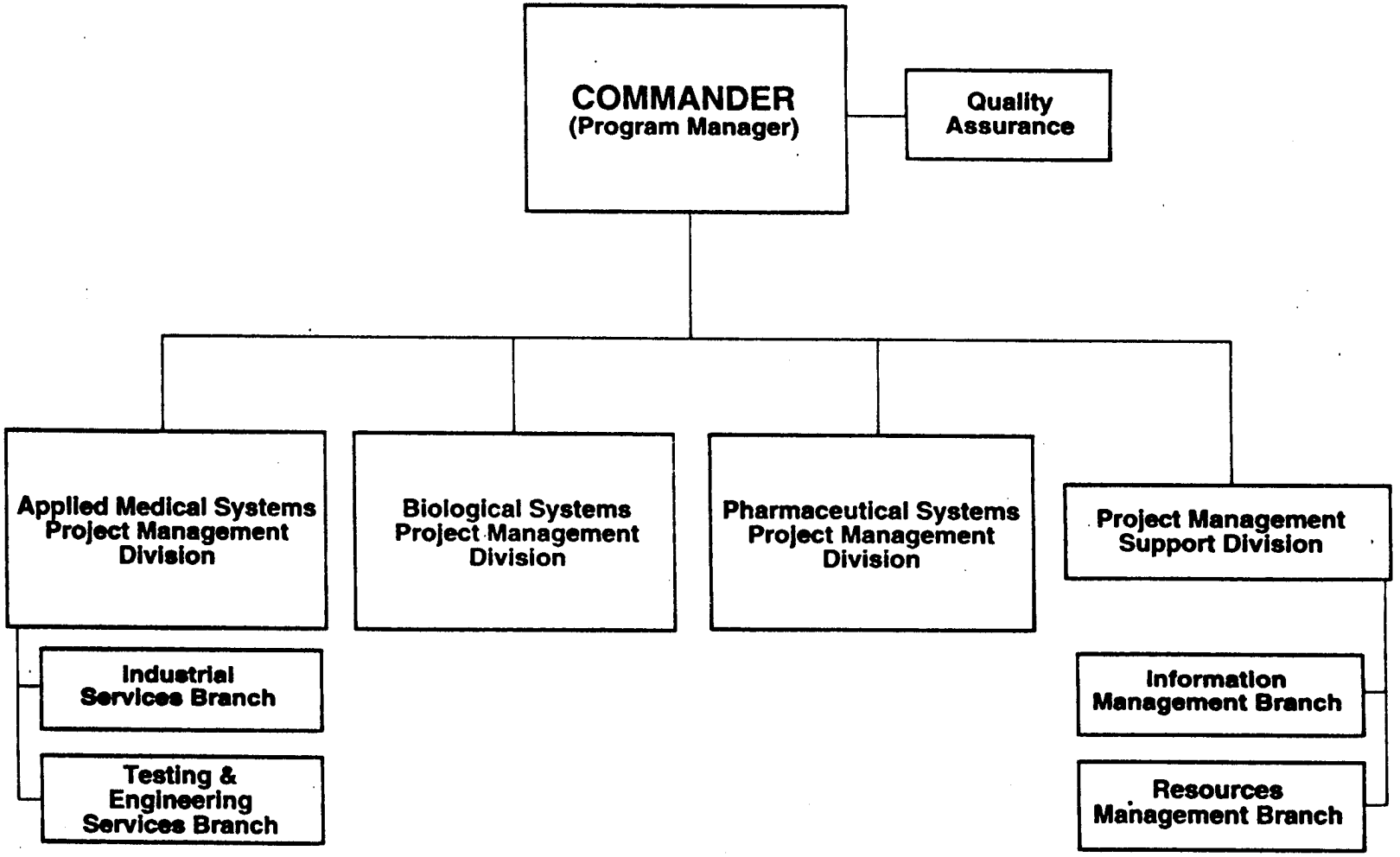
CODE LABS	ORGANIZATION
AL	U.S. Army Aeromedical Research Laboratory
BL	U.S. Army Biomedical Research and Development Laboratory
BR	U.S. Army Institute of Surgical Research
IC	U.S. Army Research Institute of Chemical Defense
ID	U.S. Army Institute of Dental Research
LR	Letterman Army Institute of Research
MR	U.S. Army Medical Research and Materiel Command
NV	Naval Medical Research and Development Command
RD	U.S. Army Medical Research Institute of Infectious Diseases
RM	U.S. Army Institute of Environmental Medicine
WR	Walter Reed Army Institute of Research

OTHER (Contractors, CRDA Partners, etc.)

3M	3M Corporation
AH	Advanced Haemotechnologies
AR	Army Research Laboratory
AV	Program Manager, Aviation Life Support Equipment
BC	Biken/Connaught
BE	Becomist
BT	Battelle
CB	U.S. Army Chemical and Biological Defense Agency
CI	Coulston, Inc.
CR	Charles River Analytics, Inc.
DC	DOD-Canada
EH	U.S. Army Environmental Hygiene Agency
EP	EPA
GT	GENENTECH
IA	University of Iowa
IM	IMMUNO-AG
IS	Israeli Defence Force
JX	Disease Vector Ecology and Control Center, Jacksonville (Navy)
LT	Lynntech, Inc.
MD	MDPH
MG	MICROGENESYS

CODE LABS	ORGANIZATION
MI	MILES
MT	Model Tech, Inc.
NH	NIH
NL	Naval Research Laboratory
NM	Naval Medical Research Institute
NR	Noise Removal System
NT	Natick Research, Development and Engineering Center
OT	Organon Teknika
PC	Porton-CAMR
PF	Pfizer, Inc.
RA	Rasor Associates, Inc.
RC	Rayex Corp
RP	Rochester Photonics
SE	Sepracor, Inc.
SI	Steris, Inc.
SK	SmithKline, Beecham, Inc.
SL	SALK
SO	Program Manager for the Soldier
SR	Southern Research Institute
ST	Sterimatics
SW	Swedish Bact. Lab
TP	Trauma Products Inc.
TR	Technical Research Associates

U. S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY



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APPENDIX C

PRODUCT TEST AND EVALUATION

During 1994, testing and engineering services were provided for eight different projects. Layouts and detail drawings were completed for three Armored Ambulance Mock-ups and the USAMMDA Litter Lift System. Level 3 drawing packages were completed for the Field OB-GYN Examination Table and the X-ray Film Development Kit. Modifications to the Armored Ambulance and the M43A1 Protective Mask Lens Carrier were provided and recorded. Significant technical advice was given on the Autoinjector TDP. Technical testing was conducted on the Modified Field X-ray Table and the STL B Space Module. Testing of the space module was in support of the Walter Reed Army Institute of Research Space Initiative involving testing biological systems in space.

TEST REPORTS

MR Number	Title	Date
1-94	Modified Field X-ray Table	Jan 94
2-94	STL B Space Module	Mar 94

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APPENDIX D

PROGRAM PRIORITIZATION MAMP LIST

PRODUCT	1994 AMEDD PRIORITY
ANTIMALARIAL DRUG, WR238605 (WR)	1
ANTIMALARIAL DRUG, AZITHROMYCIN (WR)	2
CHOLERA WHOLE CELL PLUS B SUBUNIT VACCINE (WR/SW/NV)	3
HYPERTONIC SALINE DEXTRAN (LR/TP)	4
MALARIA SPF66 BLOOD STAGE VACCINE (WR/SL)	5
TICK-BORNE ENCEPHALITIS VACCINE (RD/IM)	6
ANTIMALARIAL DRUG, HALOFANTRINE PROPHYLACTIC (WR)	7
INTRAOSSEOUS INFUSION DEVICE (LR)	8
DETOXIFIED LPS-OMP MENINGOCOCCAL GROUP B VACCINE (WR)	9
HANTAAN M-S (VACCINIA VECTORED) VACCINE (RD/SL)	10
RIFT VALLEY FEVER LIVE VACCINE (RD/SL)	11
TULAREMIA LIVE VACCINE (RD/SL)	12
HEPATITIS A VACCINE (INACTIVATED) (WR/SK)	13
ARGENTINE HEMORRHAGIC FEVER LIVE VACCINE (RD/SL)	14
CHOLERA WHOLE CELL PLUS B SUBUNIT VACCINE (ETEC INDICATION) (WR/SW)	15
NERVE AGENT PRE-TREATMENT PYRIDOSTIGMINE (IC/WR)	16
ETEC WHOLE CELL, RECOMBINANT B SUBUNIT VACCINE (WR/SW)	17
CELL CULTURE DERIVED SMALLPOX VACCINE (VACCINIA) (RD/SL)	18
SHIGELLA VACCINE, E. COLI VECTORED S. FLEXNERI (WR/IS/SL)	19
RICIN TOXIOD (RD/SL)	20
BOTULINUM TOXOID, TYPE F (PC/RD)	21
SCHISTOSOME TOPICAL ANTIPENETRANT (WR/NV/MI)	22
IMPROVED ANTHRAX VACCINE (RD/SL)	23
BOTULINUM POLYVALENT TOXIOD, TYPE A-E (MD/SL/PC)	23
TOPICAL SKIN PROTECTANT (IC/IA/BT)	25
RECOMBINANT VACCINE FOR HEMORRHAGIC FEVER RENAL SYNDROME (PUUMALA) (RD)	26
STAPH ENTEROTOXIN B TOXOID, MICROENCAPSULATED (WR/RI)	27
CHIKUNGUNYA LIVE VACCINE (RD/SL)	28
CAMPYLOBACTER VACCINE (NV)	29
SHIGELLA SONNEI VACCINE (WR)	30
SELF CONTAINED VENTILATOR (BL/AL/IC)	31
ANTILEISHMANIAL DRUG, WR6026 (WR)	32
MEDICAL/DENTAL FILMLESS IMAGING SYSTEM (MDFIS) (ID)	33
BOTULINUM TOXOID, TYPE G (PC)	34
NERVE AGENT ANTIDOTE SYSTEM (NAAS) (IC/WR/DC)	35

PRODUCT	1994 AMEDD PRIORITY
Q FEVER CMR EXTRACT VACCINE (RD/SL)	36
CYANIDE PRETREATMENT (WR/IC)	37
NERVE AGENT ANTIDOTE, MULTICHAMBERED AUTOINJECTOR (MA)	38
FIELD MEDICAL OXYGEN GENERATING AND DISTRIBUTION SYSTEM	39
BOTULISM IMMUNE GLOBULIN F(AB') 2 HEPTAVALENT, EQUINE (OT/SL)	40
BOTULISM IMMUNE GLOBULIN (HUMAN) (RD)	41
TOPICAL ANTILEISHMANIAL DRUG, PAROMOMYCIN (WR)	42
ARMORED AMBULANCE	43
LIQUID OXYGEN PRODUCTION, STORAGE AND DISTRIBUTION SYSTEM (LOPSDS)	44
ANTIMALARIAL DRUG, ARTEETHER (WR)	45
FIELD TRIAGE LIGHT (BL)	46
FIELD ANESTHESIA MACHINE	47
LOW TEMPERATURE STERILIZING SYSTEM (SI)	48
PORTABLE X-RAY TABLE	49
LIGHTWEIGHT X-RAY FILM DEVELOPMENT KIT (BL)	50
RAPID IDENTIFICATION SYSTEM (NL/NM/RD)	51
THAWED BLOOD PROCESSING SYSTEM (LR)	52
LEISHMANIA SKIN TEST (WR)	53
MICROENCAPSULATED ANTIBIOTIC, AMPICILLIN, DENTAL (ID/SR)	54
BLOWER OPTION FOR WRAP, PATIENT, CHEMICAL PROTECTIVE (BL)	55

APPENDIX E

PRODUCT LIST BY PROJECT MANAGEMENT DIVISIONS

BIOLOGICAL SYSTEMS

- Argentine Hemorrhagic Fever Live Vaccine (AHF)
- Botulism Immune Globulin (Human)
- Botulism Immune Globulin F(ab')2 Heptavalent , Equine
- C. botulinum Toxoid Types A-E
- C. botulinal Toxoid Type F
- C. botulinum Toxoid Type G
- Campylobacter Vaccine
- Chikungunya Live Vaccine
- Cholera Whole Cell +B Subunit Vaccine
- Detoxified LPS-OMP Meningococcal Group B Vaccine (WR)
- E. coli vectored S. flexneri Shigella Vaccine
- Enterotoxigenic E. coli Whole Cell +B Subunit Vaccine
- Hantaan M-S (Vaccinia-Vectored) Vaccine
- Hepatitis A Vaccine, Inactivated
- Human Immunodeficiency Virus (HIV)
- Improved Anthrax Vaccine
- Insect/Arthropod Repellent Lotion (Materiel Change)
- Leishmania Skin Test
- Malaria SPf66 Blood Stage Vaccine
- Plague Vaccine
- Q Fever CMR Extract Vaccine
- Recombinant Vaccine for Hemmorrhagic Fever Renal Syndrome (PUUMALA) (RD)
- Ricin Toxoid
- Rift Valley Fever Live Vaccine
- Shigella Sonnei Vaccine (WR)
- Smallpox Live Vaccine (RD/SL)
- Staph enterotoxin B (SEB) Toxoid, Microencapsulated
- Tick-borne Encephalitis Vaccine
- Tularemia Live Vaccine
- Vaccinia Immune Globulin (VIG)

PHARMACEUTICAL SYSTEMS

- Antimicrobial Dermal Dressing (ADD)
- Antileishmanial Drug, WR 6026
- Antimalarial Drug, WR 238605- Hypertonic Saline Dextran (HSD)
- Antimalarial Drug, Azithromycin

- Antimalarial Drug, Arteether (WR)
- Antimalarial Drug, Halofantrine, Prophylactic
- Convulsant Antidote for Nerve Agents (CANA)
- Cyanide Pretreatment (CP) WR242511 (WR/IC)
- Microencapsulated Antibiotic, Ampicillin, Dental (MEAA)
- Nerve Agent Antidote, Multichambered Autoinjector (MA)
- Nerve Agent Antidote System (NAAS)
- Nerve Agent Pretreatment, Pyridostigmine (NAPP)
- Schistosome Topical Antipenetrant (TAP)
- Topical Antileishmanial Drug, Paromomycin (WR279396)
- Topical Skin Protectant (TSP)

APPLIED MEDICAL SYSTEMS

- XM45, Aircrew Protective Mask, Vision Correction (XM45)
- Aerosol, Generator, Ultra Low Volume, Electric (AGULVE) (BL)
- Armored Ambulance (AA)
- Diagnostic Kit for Biological Warfare Agents
- Electrochemical Sterilizing System
- Expert System for Trauma Management (ESTM)
- Far Forward Suction Apparatus (FFSA)
- Field Anesthesia Machine (FAM)
- Field Medical Oxygen Generating and Distribution System (FMOGDS)
- Field OB/GYN Examination Table
- Field Triage Light (FTL) (BL)
- Field X-ray Table
- Intraosseous Infusion Development (IID)
- Lens Surfacing Generator
- Lightweight Motor Blower (LWMB)
- Lightweight X-ray Film Development Kit (BL)
- Liquid Oxygen Production, Storage and Distribution System (LOPSDS)
- Low Temperature Sterilizing System (LTSS)
- M40 Chemical Biological (CB) Protective Mask Vision Correction (Materiel Change)
- M43A1 Chemical Biological (CB) Protective Mask Vision Correction
- Medical/Dental Filmless Imaging System (MDFIS) (ID)
- Multipurpose Centrifuge (TR/BL)
- Portable Rugged Laser Optometer (PRLO)
- Self-Contained Ventilator (SCV)
- Sprayer, Pesticide, Electric, Liquid (SPEL) (BL)
- Thawed Blood Processing System (TBPS)
- Vision Corrective Eyewear (VCE)
- Water Quality Analysis Set - Preventive Medicine (BL)
- X-ray System, Dental, Miniature (ID)

APPENDIX F

KEY PERSONNEL AND UNIT STRENGTH

Key Personnel:

Position	Name	Date
Commander	COL G.E. Lewis, Jr.	1 Jan 94 to 31 Dec 94
Deputy Commander	LTC James R. Stewart	1 Jan 94 to 31 Dec 94
Project Manager/BSPMD	Dr. W.E. Brandt	1 Jan 94 to 31 Dec 94
Project Manager/AMSPMD	Dr. J.H. Nelson	1 Jan 94 to 31 Dec 94
Project Manager/PSPMD	Dr. R.E. Clawson	1 Jan 94 to 31 Dec 94
Chief/PMSD	Mr. W.R. Ferguson, Jr.	1 Jan 94 to 31 Dec 94
Chief, Quality Assurance Office	Ms. L.A. Walton	1 Jan 94 to 31 Dec 94
Administrative Officer	Ms. D.W. Albright	1 Jan 94 to 31 Dec 94

Strength: As of 31 December 1994:

	Military	Civilian	Total
Required	21	63	84
Authorized	20	53	73
Actual	12	49	61

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APPENDIX G

FISCAL PROGRAM EXECUTION

DIRECT

Project	Allotment ($000)	PERCENT In-House OBL	In-House DISB	Extramural OBL	Extramural DISB	Total OBL	Total DISB
808	7,745	100	69	97	33	98	48
811	1,836	100	61	100	66	100	65
836	920	100	91	81	27	100	90
837	0						
993	5,454	98	74	100	17	99	35
Total 6.3B	15,955	99	74	99	32	99	48
812	6,205	99	36	36	100	85	84
832	2,582	100	39	89	9	96	28
834	306	0	0	100	16	100	16
848	1,074	100	98	100	29	100	43
849	4,220	100	51	95	42	98	47
Total 6.4	14,386	100	47	98	62	98	58
Total Program	30,341	100	63	98	47	99	53

REIMBURSABLE

Project	Allotment ($000)	PERCENT In-House OBL	In-House DISB	Extramural OBL	Extramural DISB	Total OBL	Total DISB
JPO-BD D/V	4,613	100		100		100	
EMD	215	100		100		100	